TO: Clerk's Office
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

APPLICATION FOR LEAVE
TO FILE DOCUMENT UNDER SEAL

****
U.S. ex el. Pamela Arriazola

-v.- **06-3232**
Docket Number

Amgen, Inc. et al.
****

SUBMITTED BY: Plaintiff__X__ Defendant____ DOJ ____
Name:_Pamela Arriazola_____
Firm Name: Kenney & McCafferty_____
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Blue Bell, PA 19422_____
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INDICATE UPON THE PUBLIC DOCKET SHEET: YES____ NO__X__
If yes, state description of document to be entered on docket sheet:

A) If pursuant to a prior Court Order:
Docket Number of Case in Which Entered: **_06-3232**
Judge/Magistrate Judge: The Honorable Sterling Johnson, Jr. __
Date Entered: April 5, 2011_____

B) If a new application, the statute, regulation, or other legal basis that authorizes filing under seal

ORDERED SEALED AND PLACED IN THE CLERK'S OFFICE, AND MAY NOT BE UNSEALED UNLESS ORDERED BY THE COURT.

DATED: , NEW YORK

U.S. DISTRICT JUDGE/U.S. MAGISTRATE JUDGE

RECEIVED IN CLERK'S OFFICE_____
DATE

MANDATORY CERTIFICATION OF SERVICE:
A.) ___ A copy of this application either has been or will be promptly served upon all parties to this action, **B.)** _X__ Service is excused by 31 U.S.C. 3730(b), or by the following other statute or regulation:_____; or **C.)** ____This is a criminal document submitted, and flight public safety, or security are significant concerns. (Check one)

9.12.11
DATE

M. Tony Deming
SIGNATURE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel. [UNDER SEAL] **Plaintiffs,** **v.** **[UNDER SEAL]** **Defendants.**	§ § § § § § § § § § § § § § § § § § § §	**CIVIL ACTION No.** **06-3232** **EX PARTE MOTION FOR LEAVE TO FILE THIRD AMENDED COMPLAINT** **FILED UNDER SEAL** **JURY TRIAL DEMANDED** **(Johnson, J.)** **(Levy, MJ)**

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES *ex rel.* PAMELA ARRIAZOLA; STATE OF ILLINOIS *ex rel.* PAMELA ARRIAZOLA; STATE OF CALIFORNIA *ex rel.* PAMELA ARRIAZOLA; STATE OF DELAWARE *ex rel.* PAMELA ARRIAZOLA; STATE OF FLORIDA *ex rel.* PAMELA ARRIAZOLA; STATE OF GEORGIA *ex rel.* PAMELA ARRIAZOLA; STATE OF HAWAII *ex rel.* PAMELA ARRIAZOLA; STATE OF INDIANA *ex rel.* PAMELA ARRIAZOLA; STATE OF LOUISIANA *ex rel.* PAMELA ARRIAZOLA; STATE OF MASSACHUSETTS *ex rel.* PAMELA ARRIAZOLA; STATE OF MONTANA *ex rel.* PAMELA ARRIAZOLA; STATE OF MICHIGAN *ex rel.* PAMELA ARRIAZOLA; STATE OF NEW HAMPSHIRE *ex rel.* PAMELA ARRIAZOLA; STATE OF NEW JERSEY *ex rel.* PAMELA ARRIAZOLA; STATE OF NEW MEXICO *ex rel.* PAMELA ARRIAZOLA; STATE OF NEW YORK *ex rel.* PAMELA ARRIAZOLA; STATE OF OKLAHOMA *ex rel.* PAMELA ARRIAZOLA; STATE OF RHODE ISLAND *ex rel.* PAMELA ARRIAZOLA; STATE OF TENNESSEE *ex rel.* PAMELA ARRIAZOLA; STATE OF TEXAS *ex rel.* PAMELA ARRIAZOLA; COMMONWEALTH OF VIRGINIA *ex rel.* PAMELA ARRIAZOLA; DISTRICT OF COLUMBIA *ex rel.* PAMELA ARRIAZOLA; and, PAMELA ARRIAZOLA individually, **Plaintiffs,** **v.** **AMGEN, INC., ONCOLOGY SUPPLY, INC, AMERISOURCE BERGEN SPECIALTY GROUP, INC, CARDINAL HEALTH SPECIALTY PHARMACEUTICAL DISTRIBUTION, INTERNATIONAL ONCOLOGY NETWORK, NATIONAL ONCOLOGY ALLIANCE, ONCOLOGY THERAPEUTICS, INC.,** **Defendants.**	§	**CIVIL ACTION** **06-3232** **EX PARTE MOTION FOR LEAVE TO FILE THIRD AMENDED COMPLAINT** **FILED UNDER SEAL** **JURY TRIAL DEMANDED** **(Johnson, J.)** **(Levy, MJ)**

Plaintiff-Relator's *Ex Parte* Motion for Leave to File Third Amended Complaint

Plaintiff-Relator Pamela Arriazola ("Plaintiff"), by and through her undersigned counsel, hereby respectfully requests this Honorable Court to grant leave to file the proposed Third Amended Complaint attached as Exhibit 1 pursuant to Federal Rule of Civil Procedure 15(a)(2). In support of this Motion Plaintiff avers as follows:

1. Federal Rule of Civil Procedure 15(a) requires that leave to file an amended complaint be "freely given when justice so requires." This standard is readily met here. The Third Amended Complaint clarifies the issues, adds states as plaintiffs that have enacted False Claims Acts after the Second Amended Complaint was filed and adds new evidence identified by Plaintiff since the filing of the Second Amended Complaint. The Third Amended Complaint also adds Amerisource Bergen Corporation as a defendant. Amerisiource Bergen Corporation is the parent company of Defendant Amerisource Bergen Specialty Group, Inc. as is liable for the acts of its subsidiary.

2. Further, granting leave will assist the United States' government in fully investigating the defendants' schemes as alleged in the complaint so as to remedy the frauds perpetrated by defendants on the United States and the Plaintiff States.

3. Accordingly, granting leave to file the Third Amended Complaint is consistent with Fed.R.Civ.P. 15(a)(2).

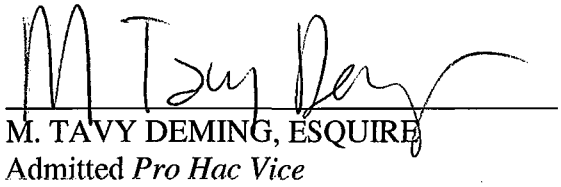
4. The Supreme Court of the United States determined that "[i]n the absence of . . . undue delay, bad faith or dilatory motive . . . undue prejudice . . . futility of amendment, etc.--the leave sought should . . . be 'freely given.' " *Foman v. Davis*, 371 U.S. 178, 182 (1962).

5. Defendants shall suffer no prejudice from the filing of Plaintiff's Third Amended Complaint as this matter remains under seal and there is no other reason Plaintiff should not be grant leave

WHEREFORE, Plaintiff-Relator Arriazola respectfully requests this Honorable Court enter the proposed Order and grant leave to file the proposed Third Amended Complaint.

Respectfully submitted,

KENNEY & McCAFFERTY, PC



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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES *ex rel.* PAMELA ARRIAZOLA; STATE OF ILLINOIS *ex rel.* PAMELA ARRIAZOLA; STATE OF CALIFORNIA *ex rel.* PAMELA ARRIAZOLA; STATE OF DELAWARE *ex rel.* PAMELA ARRIAZOLA; STATE OF FLORIDA *ex rel.* PAMELA ARRIAZOLA; STATE OF GEORGIA *ex rel.* PAMELA ARRIAZOLA; STATE OF HAWAII *ex rel.* PAMELA ARRIAZOLA; STATE OF INDIANA *ex rel.* PAMELA ARRIAZOLA; STATE OF LOUISIANA *ex rel.* PAMELA ARRIAZOLA; STATE OF MASSACHUSETTS *ex rel.* PAMELA ARRIAZOLA; STATE OF MONTANA *ex rel.* PAMELA ARRIAZOLA; STATE OF MICHIGAN *ex rel.* PAMELA ARRIAZOLA; STATE OF NEW HAMPSHIRE *ex rel.* PAMELA ARRIAZOLA; STATE OF NEW JERSEY *ex rel.* PAMELA ARRIAZOLA; STATE OF NEW MEXICO *ex rel.* PAMELA ARRIAZOLA; STATE OF NEW YORK *ex rel.* PAMELA ARRIAZOLA; STATE OF OKLAHOMA *ex rel.* PAMELA ARRIAZOLA; STATE OF RHODE ISLAND *ex rel.* PAMELA ARRIAZOLA; STATE OF TENNESSEE *ex rel.* PAMELA ARRIAZOLA; STATE OF TEXAS *ex rel.* PAMELA ARRIAZOLA; COMMONWEALTH OF VIRGINIA *ex rel.* PAMELA ARRIAZOLA; DISTRICT OF COLUMBIA *ex rel.* PAMELA ARRIAZOLA; and, PAMELA ARRIAZOLA individually, **Plaintiffs,** **v.** **AMGEN, INC., ONCOLOGY SUPPLY, INC, AMERISOURCE BERGEN SPECIALTY GROUP, INC, CARDINAL HEALTH SPECIALTY PHARMACEUTICAL DISTRIBUTION, INTERNATIONAL ONCOLOGY NETWORK, NATIONAL ONCOLOGY ALLIANCE, ONCOLOGY THERAPEUTICS, INC.,** **Defendants.**	§	**CIVIL ACTION** **06-3232** **FILED UNDER SEAL** **JURY TRIAL DEMANDED** **(Johnson, J.)** **(Levy, MJ)**

PROPOSED ORDER

AND NOW this _____ day of _____, 2011, in response Relator-Plaintiff's *Ex Parte* Motion for Leave to File Third Amended Complaint Under Seal, it is hereby **ORDERED** that the Motion for Leave and attached Fourth Amended *qui tam* Complaint, and all other pleadings and documents subsequently submitted hereafter shall be filed in camera and under seal and remain so until this Court orders otherwise, but not less than 60 days.

It is hereby further **ORDERED** that the qui tam Complaint shall not be served on Defendants until this Court so orders.

BY THE COURT:

_____

HONORABLE STERLING JOHNSON, JR.
United States District Judge, E.D.N.Y.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel. [UNDER SEAL] **Plaintiffs,** **v.** **[UNDER SEAL]** **Defendants.**	§ §	**CIVIL ACTION No.** **06-3232** **THIRD AMENDED COMPLAINT** **FILED UNDER SEAL** **JURY TRIAL DEMANDED** **(Johnson, J.)** **(Levy, MJ)**

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ex rel. PAMELA ARRIAZOLA, STATE OF CALIFORNIA, ex rel. PAMELA ARRIAZOLA, STATE OF COLORADO, ex rel. PAMELA ARRIAZOLA, STATE OF CONNECTICUT, ex rel. PAMELA ARRIAZOLA, STATE OF DELAWARE, ex rel. PAMELA ARRIAZOLA, STATE OF FLORIDA, ex rel. PAMELA ARRIAZOLA, STATE OF GEORGIA, ex rel. PAMELA ARRIAZOLA, STATE OF HAWAII, ex rel. PAMELA ARRIAZOLA, STATE OF ILLINOIS, ex rel. PAMELA ARRIAZOLA, STATE OF INDIANA, ex rel. PAMELA ARRIAZOLA, STATE OF LOUISIANA, ex rel. PAMELA ARRIAZOLA, STATE OF MARYLAND, ex rel. PAMELA ARRIAZOLA, COMMONWEALTH OF MASSACHUSETTS, ex rel. PAMELA ARRIAZOLA, STATE OF MICHIGAN, ex rel. PAMELA ARRIAZOLA, STATE OF MINNESOTA, ex rel. PAMELA ARRIAZOLA, STATE OF MONTANA, ex rel. PAMELA ARRIAZOLA, STATE OF NEW YORK, ex rel. PAMELA ARRIAZOLA, STATE OF NORTH CAROLINA, ex rel. PAMELA ARRIAZOLA, STATE OF NEVADA, ex rel. PAMELA ARRIAZOLA, STATE OF NEW HAMPSHIRE, ex rel. PAMELA ARRIAZOLA, STATE OF NEW JERSEY, ex rel. PAMELA ARRIAZOLA, STATE OF NEW MEXICO, ex rel. PAMELA ARRIAZOLA, STATE OF OKLAHOMA, ex rel. PAMELA ARRIAZOLA, STATE OF RHODE ISLAND, ex rel. PAMELA ARRIAZOLA, STATE OF TENNESSEE, ex rel. PAMELA ARRIAZOLA, STATE OF TEXAS, ex rel. PAMELA ARRIAZOLA, COMMONWEALTH OF VIRGINIA, ex rel. PAMELA ARRIAZOLA, STATE OF WISCONSIN, ex rel. PAMELA ARRIAZOLA, NEW YORK CITY, ex rel. PAMELA ARRIAZOLA, CITY OF CHICAGO, ex rel., and the DISTRICT OF COLUMBIA, ex rel. PAMELA ARRIAZOLA; and PAMELA ARRIAZOLA individually, **Plaintiffs,** **v.** **AMGEN, INC., ONCOLOGY SUPPLY, INC, AMERISOURCE BERGEN SPECIALTY GROUP, INC, AMERISOURCE BERGEN CORP., CARDINAL HEALTH SPECIALTY PHARMACEUTICAL DISTRIBUTION, INTERNATIONAL ONCOLOGY NETWORK, NATIONAL ONCOLOGY ALLIANCE, ONCOLOGY THERAPEUTICS, INC.,** **Defendants.**	§	**CIVIL ACTION No.** **06-3232** **THIRD AMENDED COMPLAINT** **FILED UNDER SEAL** **JURY TRIAL DEMANDED** **(Johnson, J.)** **(Levy, MJ)**

THIRD AMENDED COMPLAINT

This action is brought by Relator Pamela Arriazola on behalf of the United States of America (the "United States") and the District of Columbia, the City of New York, the City of Chicago, and the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin (collectively the "Plaintiff States"), and Pamela Arriazola individually (hereinafter "Arriazola"), allege as follows in support of this Third Amended Complaint against the Defendants Amgen, Inc. ("Amgen"), Oncology Supply Inc., Amerisource Bergen Specialty Group, Amerisource Bergen Corp, Cardinal Health Specialty Pharmaceutical Distribution, International Oncology Network, National Oncology Alliance and Oncology Therapeutics, Inc. (hereinafter collectively the "Defendants") based upon the personal knowledge of and documents in the possession of Arriazola:

I. NATURE OF THE CASE

1. This is an action by both the United States and the Plaintiff States (the "Government Plaintiffs"), by and through the Relator-Plaintiff Arriazola against Amgen and the remaining Defendants to redress violations of the False Claims Act, 31 U.S.C. §§ 3729-3730 and the analogous laws of the Plaintiff States.

2. Amgen is a California corporation with its principal place of business located at One Amgen Center Drive, Thousand Oaks, California. In 2002, Amgen acquired Immunex Corporation ("Immunex"), a Washington corporation with its principal place of business at 51 University Street, Seattle, Washington.

3. Amgen and Immunex (collectively, "Amgen") are highly diversified healthcare companies that individually, and in combination with one another, engage in the business of manufacturing, distributing, marketing and selling prescription drugs purchased and/or reimbursed by the Government Plaintiffs, through, *inter alia*, the Medicare and Medicaid programs. The Amgen drugs at issue in this case include Epogen (epoetin alfa), Aranesp (darbepoetin alfa), and Neupogen (filgrastim (G-CSF)), which are used in the treatment of patients undergoing cancer chemotherapy, in addition to Enbrel (etanercept) and Kineret (anakinra), which are used to treat rheumatoid arthritis, Neulasta (pegfilgrastim), which is used to reduce the risk of infection in some cancer patients and Sensipar (cinacalcet HCI), which is used to help treat dialysis patients with imbalances of phosphorus, calcium, and PTH, known as secondary hyperparathyroidism.

4. From December 1999 until May 9, 2005, Arriazola had been employed by Amgen as a Pharmaceutical Sales Representative (PSR) and Health Systems Manger (HSM).

5. In her capacity as a Pharmaceutical Sales Representative from December 1998 through January 2003, Arriazola was responsible for the marketing of Amgen pharmaceutical products in the Illinois region. Her client base consisted of physician practice groups and community hospitals. During this period of time, she regularly attended various Regional and National Sales meetings, typically held from 2 to 4 times per year. The information, materials and training provided at these meetings confirmed the uniform, nationwide scope of Amgen's unlawful schemes with respect to its drugs complained of herein.

6. From January, 2003 through May 9, 2005, Arriazola was a HSM responsible

for the sales and marketing of Amgen's products to academic and teaching hospitals.

II. JURISDICTION AND VENUE

7. This is a civil action arising under the laws of the United States to redress violations of 31 U.S.C. §§3729-3730. This Court has jurisdiction over the subject matter of this action: (i) pursuant to 31 U.S.C. §3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730; (ii) pursuant to 28 U.S.C. §1331, which confers federal subject matter jurisdiction; and (iii) pursuant to 28 U.S.C. §1345, because the United States is a plaintiff. This Court has pendant jurisdiction over the claims brought under the Plaintiff States' laws analogous to the Federal False Claims Act, cited herein, pursuant to 28 U.S.C. §1367.

8. This court has jurisdiction over Defendants under 31 U.S.C. §3732(a) because they can be found in, are authorized to transact business in, and are now transacting business in this District. In addition, acts proscribed by 31 U.S.C. §3729 have occurred in this District.

9. Venue is proper in the Eastern District of New York because Defendants conduct business in this District and, upon information and belief, acts giving rise to this action occurred within this District.

10. This suit is not based upon prior public disclosures of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation or in a Government Accounting Office or Auditor General's report, hearing, audit, or investigation, or from the news media.

11. To the extent that there has been a public disclosure unknown to Arriazola, she is an original source under 31 U.S.C. §3730 (e)(4) and the analogous

provisions of the Plaintiff States' whistleblower statutes. She has direct and independent knowledge of the information on which the allegations are based and voluntarily provided the information to the government before filing a *qui tam* action based on the information.

12. At the time she filed her original complaint in this action, Arriazola concurrently provided to the Attorney General of the United States and to the United States Attorney for the Eastern District of New York a statement summarizing known material evidence and information related to this Complaint, in accordance with the provisions of 31 U.S.C. §3730(b)(2). The disclosure statement was and is supported by material evidence.

III. PARTIES

13. The United States of America and the Plaintiff States (the "Government Plaintiffs") are the plaintiffs for whom recovery is sought for false and fraudulent claims submitted to Medicare, Medicaid and other government-funded healthcare programs, including the Railroad Retirement Medicare Program, the Indian Health Service, the Federal Employee Health Benefit Plans, Tri-Care (formerly CHAMPUS), CHAMP VA, and the State Legal Immigrant Assistance Grants ("SLIAG").

14. Plaintiff and relator Pamela Arriazola is a citizen and resident of the State of Illinois. She brings this action on her own behalf and on behalf of the Government Plaintiffs pursuant to 31 U.S.C. §3730(b)(1) and the analogous laws of the Plaintiff States.

15. Defendant Amgen, a California corporation, is a research-based, global pharmaceutical company, with its principal place of business located at One Amgen Center Drive, Thousand Oaks, California.

16. Defendant Oncology Supply, Inc. (hereinafter OSI) is a wholly-owned subsidiary of Amerisource Bergen, Specialty Group, Inc. (hereinafter ABSG). OSI is an Alabama corporation with its principal place of business located at 2801 Horace Shepard drive, Dothan, Alabama, 36303. OSI is a pharmaceutical wholesaler that entered into contracts with Amgen to purchase various pharmaceutical products for the "list price" of the drugs. Further, OSI has accepted kickbacks from Amgen in the form of rebates and chargebacks in exchange for purchasing Amgen products.

17. Defendant ABSG is a Texas corporation with its principal place of business located at 4006 Belt Line Road, Addison, TX 75000. ABSG is a pharmaceutical wholesaler that entered into contracts with Amgen to purchase various pharmaceutical products for the "list price" of the drugs. ABSG has accepted kickbacks from Amgen in the form of rebates and chargebacks in exchange for purchasing Amgen products.

18. Defendant Amerisource Bergen Corporation (hereinafter ABC), a Delaware corporation, is a global pharmaceutical service company, focusing on the pharmaceutical supply chain, proving drug distribution and related services to pharmaceutical manufacturers and healthcare providers. Its principal place of business is located at 1300 Morris Drive, Chesterbrook, PA 19087.

19. Defendant Cardinal Health, Specialty Pharmaceutical Distribution (Cardinal Health SPD) is a wholly-owned division of Cardinal Health, Inc. SPD's principal place of business is located at 401 Mason Road, La Vergne, TN 37081. Cardinal Health, SPD is a pharmaceutical wholesaler that entered into contracts with Amgen to purchase various pharmaceutical products for the "list price" of the drugs. Further, Cardinal Health SPD has

accepted kickbacks from Amgen in the form of rebates and chargebacks in exchange for purchasing Amgen products.

20. Defendant International Oncology Network (hereinafter ION) is a Maryland corporation with its principal place of business located at The World Trade Center, 11th floor, 401 East Pratt Street, Baltimore, MD 21202. ION is ostensibly a group purchasing organization ("GPO"). A true GPO is a group of doctors, clinics, hospitals or other health care providers, organized for many purposes, including the ability to make large volume purchases of supplier products at substantial discounts. Amgen entered into improper contracts with ION and upon information and belief, ION does not qualify as a GPO and instead is a marketing arm of Amgen through which Amgen funneled kickbacks to customers to avoid Best Price Reporting obligations as well as to avoid compliance with the AKS. Further, ION has accepted kickbacks from Amgen in the form of rebates and chargebacks in exchange for purchasing Amgen products.

21. Defendant National Oncology Alliance (hereinafter NOA) is a Delaware corporation with its principal place of business located at Suite 350, 750 Lindaro Street, San Rafael, California, 94901. NOA is ostensibly a group purchasing organization ("GPO"). A true GPO is a group of doctors, clinics, hospitals or other health care providers, organized for many purposes, including the ability to make large volume purchases of supplier products at substantial discounts. Amgen entered into improper contracts with NOA and upon information and belief, NOA does not qualify as a GPO and instead is a marketing arm of Amgen through which Amgen has funneled kickbacks to customers to avoid Best Price Reporting obligations as well as to avoid compliance with the AKS. Further, NOA has accepted kickbacks from Amgen in the form of rebates and chargebacks in exchange for

purchasing Amgen products. Further, NOA has accepted kickbacks from Amgen in the form of rebates and chargebacks in exchange for purchasing Amgen products.

22. Defendant Oncology Therapeutics, Inc. (OTN) is a California corporation with its principal place of business located at Suite 500, 399 Oyster Point Boulevard, South San Francisco, CA 94080. OTN is a pharmaceutical wholesaler that entered into contracts with Amgen to purchase various pharmaceutical products for the "list price" of the drugs. Further, OTN has accepted kickbacks from Amgen in the form of rebates and chargebacks in exchange for purchasing Amgen products.

IV. BACKGROUND

23. Defendant Amgen has engaged in an unfair and deceptive marketing and sales scheme to provide improper incentives and inducements to medical providers and other purchasers of Amgen's drugs calculated to increase sales of those drugs at artificially inflated prices throughout the United States, to the detriment of the Government Plaintiffs and taxpayers.

24. During the time that Arriazola served as a Health Systems Manager, from January of 2003 through May 9, 2005, she was responsible for marketing to academic and teaching hospitals. She is thus fully aware of the numerous practices employed by Amgen to improperly "market the spread" to these hospitals through various discount and rebate schemes, many of which were reduced to written form in various contracts.

25. Amgen supplied Arriazola with numerous tools, such as computerized spread sheets demonstrating the profit margins or "spread" that hospitals could realize if they used Amgen products instead of Amgen's competitor's products. For instance, Amgen

used the computerized spreadsheets to demonstrate the financial benefit of using Aranesp as opposed to Ortho McNeil's product Procrit.

26. The use of computerized spreadsheets to market the spreads to hospitals was but one example of Amgen's aggressive and improper marketing the profit margins that Amgen creates for the client hospitals, clinics and other healthcare providers by Amgen's improper manipulation of prices for its products through discount and rebate schemes that were unreported to the Government Plaintiffs.

27. These unfair and deceptive marketing and sales schemes caused harm to the Government Plaintiffs by causing the government-funded healthcare programs to pay more for Amgen's drugs than it otherwise would have paid in the absence of Amgen's unlawful conduct.

28. Amgen engaged in at least six (6) schemes in furtherance of its improper marketing practices that, *inter alia*, caused the submission of false claims to government-funded healthcare programs:

- marketing and promoting prescription drugs "off-label" without proper authority or medical support in violation of Federal Drug Administration rules and regulations;
- Intentionally establishing (through false price reporting discussed *infra* and promoting "spreads" on prescription drugs ("marketing the spread");
- providing materials and goods to existing customers with the knowledge and/or expectation that medical providers and other purchasers would increase and maintain their volume of purchases of Amgen products, with these purchases subsequently billed to the Government Plaintiffs;
- providing other financial incentives and inducements, as detailed more fully herein, to induce sales of Amgen's drugs at artificially inflated prices; and,
- false or fraudulent reporting of the actual "best price" or "average manufacturer's price" for Amgen's drugs in quarterly CMS Best Price Reports

submitting pursuant to Amgen's Rebate Agreement with CMS, and instead (i) reporting of higher prices and (ii) excluding discounts and other inducements described herein offered to hospitals and clinics that resulted in lower prices than the prices reported to the Medicaid Program as well as resulted in Amgen decreasing or avoiding entirely its obligations to make quarterly rebate payments to the Medicaid program.

- Manipulation of ASP for Amgen's drugs.

29. Each of these acts and practices, and Defendants' respective roles therein, is described more fully below.

V. FEDERAL LAW PROHIBITS KICKBACKS TO INDUCE PURCHASES OF DRUGS PAID FOR BY GOVERNMENT HEALTH CARE PROGRAMS.

30. The Medicare and Medicaid Fraud and Abuse Statute (Statute) was first enacted under the Social Security Act in 1977. The Statute imposes criminal penalties on whomever:

> offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2)(B).

31. This provision, known as the Anti-Kickback Statute, and the analogous laws of the Plaintiff States, applies to Amgen, which manufactures drugs included on the Medicare and Medicaid formularies, and formularies of other government-funded healthcare programs. Accordingly, the Anti-Kickback Statute and the Plaintiff States' laws prohibited Amgen from engaging in the mere act of offering illegal remuneration, regardless of whether the inducement is ultimately accepted by the buyer of Amgen's drugs. Such inducements cause financial and patient harm because they encourage unnecessary

treatments, influence the free exercise of medical judgment by providers, limit patient options and lead to higher payments for medical services by government-funded healthcare programs. Further, the AKS prohibits the remaining Defendants from accepting Amgen's kickbacks in exchange for purchasing Amgen drugs, as well as the remaining Defendants' acts passing through Amgen's kickbacks to end-customers such as hospitals and clinics. The AKS further defines "remuneration" to include "transfers of items or services for free or for other than fair market value." *Id.* § 1320a-7a(i)(6). Perhaps underscoring the breadth of the statutory definition, the HHS OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (1991), broadly define the term "remuneration" as "anything of value in any form whatsoever." *See also* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 66 Fed. Reg. 23731, 23734 (May 5, 2003) (AKS addresses the offer or payment of "anything of value"). Accordingly, the exchange of free goods as well as the exchange of money can give rise to violations of the AKS where the intent element is met.

32. Federal and state law is clear that a prescription drug reimbursement claim is ineligible for reimbursement where the entity submitting the claim accepted a kickback where the kickback was intended to induce the purchase of the drug. Accordingly, such a claim, if submitted, is false as that term is defined by the Federal False Claims Act and the analogous laws of the Plaintiff States.

33. The Patient Protection and Affordable Care Act, Publ. L No. 111-148, 124 Stat. 119 § 6402(f)(1) (2010) ("PPACA"), which became law on March 23, 2010, leaves no doubt that violations of the AKS give rise to a violation of the FCA, by providing: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the False Claims Act]." In other words, pursuant to the

PPACA, claims for items or services billed to government-funded healthcare programs (including Medicare) "resulting from" a violation of the anti-kickback statute are "false or fraudulent claims" under the FCA.

34. The PPACA also clarified the intent requirement for the AKS, and now provides that "a person need not have actual knowledge of this section or specific intent to commit a violation" of the AKS in order to be found guilty of a "willful violation." Accordingly, proof that a Defendant knew of and specifically intended to violate the AKS is not required, instead proof that the Defendant intended to perform the actions that violated the anti-kickback statute gives rise to liability.

35. At all times relevant to this complaint, compliance with the Anti-Kickback Statute has been a condition of participation for a health care provider under Medicare. Moreover, compliance with the AKS is a *condition of payment* for claims made to Medicare for reimbursement for services, including home health services.

36. For example, under 42 U.S.C. § 1395y(a)(1)(A), "nonpayment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury."

37. Kickbacks are, by definition, not "reasonable and necessary for the diagnosis or treatment of illness or injury."

38. Amgen, by and through the act of offering and paying cash and in kind kickbacks to clients as alleged herein, caused to be submitted false claims to the Government Plaintiffs seeking reimbursement for Amgen's drugs. These false claims were submitted by Amgen's clients which accepted Amgen's kickbacks – directly or directly – hospitals, clinics and other medical providers and alleged herein.

39. The remaining Defendants, which are GPOs and wholesalers, played an integral role in the kickback scheme by accepting and passing through Amgen's kickbacks in the form of rebates, chargebacks and administrative fees and passing part of those kickbacks through to ultimate Amgen purchaser/clients. The remaining Defendants, by and through their unlawful conduct, also caused these clients to submit false claims tainted by kickbacks to the Government Plaintiffs by and through the *inter alia* Medicaid and Medicare programs.

VI. MARKETING AND PROMOTING THE "SPREAD"

40. Up until 2005, reimbursement for prescription drugs by government-funded healthcare programs such as Medicare and Medicaid was based, in whole or part, on the "Average Wholesale Price," or the "AWP." The AWP is not an "average" of "wholesale" or manufacturers' pricing, as the names suggests, but instead is a price that is controlled and set by drug manufacturers, including Amgen.

41. In 2005, government-funded healthcare programs such as Medicare and Medicaid went to an ASP– based reimbursement model.

42. Plaintiff Arriazola is aware, based upon her training and knowledge of Amgen reimbursement policies from 1990 to 2005, that AWP was set as 25% above the list price of Amgen products, so that a guaranteed profit margin was built in for Amgen product usage by purchasing providers.

43. Amgen reported the AWP for its drugs to various pricing compendia, such as the *Red Book* and *First Data Bank*, which, in turn, published these AWPs in reference books used and relied upon by both the public and private sector. Medical providers and other purchasers of Amgen's drugs received reimbursement for prescriptions filled with Amgen's

drugs through Medicare and Medicaid (among other government-funded healthcare programs) based upon the AWP reported by Amgen.

44. The AWPs reported by Amgen did not represent prices actually paid by any medical provider or other purchaser of Amgen's drugs.

45. Instead, Amgen purposefully inflated the AWP for its drugs so that government-funded healthcare programs would pay reimbursement to Amgen's end customers far in excess of any price actually paid by such customers when they acquired Amgen drugs.

46. Thus, Amgen controlled the price of its drugs via its reporting of AWP to pricing compendia, upon which the Government Plaintiffs' relied in paying claims seeking reimbursement for the purchase of Amgen drugs up through 2005.

47. In addition to controlling and setting the price used by the Government Plaintiffs to calculate reimbursement, Amgen also set and controlled the prices it charged purchasers of its drugs through the aforementioned direct and indirect marketing and sales schemes (including GPOs and wholesalers). These acquisition costs, *i.e.* the costs to acquire Amgen's drugs, are far below the AWP-based prices paid by Medicare and Medicaid.

48. Amgen deeply discounted the acquisition costs for its drugs far below the AWP-based prices paid by Medicare and Medicaid for these same drugs to create "spreads" between the acquisition costs and the AWPs. Included in these lower prices were off-invoice discounts ("OIDs") that were provided to customers to induce purchases of Amgen's products.

49. Amgen intentionally created a large "spread" between the acquisition cost and the reimbursement paid by government-funded healthcare programs so its customers

could earn a profit for each prescription of Amgen drugs written to the beneficiaries of these government-funded programs. Amgen's goal was to make its drugs more profitable to prescribe than competing manufacturer's drugs such as Ortho Biotech's Procrit.

50. Amgen also orchestrated a scheme whereby it concealed the existence of other rebates by passing rebates and discounts through GPOs and wholesalers to the end customer. By using this passthrough system, Amgen was able to conceal these discounts and rebates for price reporting requirements.

51. Amgen sales representatives carried out the company's scheme by explaining to medical providers and other customers that they could *personally* profit from prescribing Amgen products. For example, Amgen sales representatives were directed to explain to medical providers that they could generate substantial income by prescribing Aranesp injections which are used to treat certain types of anemia.

52. Arriazola has personal knowledge that Amgen accomplished this by describing to medical providers the "spread" between (1) the per unit allowable amount reimbursed by Medicare and (2) the lower quantity discount price actually paid by the medical provider to Amgen. Projections generated by Amgen tailored to specific medical providers and used during sales calls showed, for instance, that a doctor could obtain a profit from Medicare of almost $100 dollars for each 100 mcg Aranesp injection purchased from Amgen.

53. By controlling and inflating the acquisition cost paid by customers and the end payors, such as the Government Plaintiffs through the Medicare and Medicaid programs, Amgen created and manipulated the spreads for its drugs purchased by providers

and other customers by controlling and manipulating the discounts and rebates that affect the spreads.

54. Amgen has unlawfully promoted and marketed these "spreads," and the profits to be realized there from, to their customers throughout the relevant time period.

55. Since Amgen has controlled both the prices paid by its customers [*i.e.*, the acquisition costs] and the prices paid by their customers' customers [*i.e.*, the AWPs], they have promoted the spread between these two prices as an incentive or inducement to prescribe and sell its drugs.

56. Amgen's marketing and sales practices have resulted in a perverted "competitive" environment whereby Amgen has sought to continually raise, inflate and fix the AWPs for their drugs, which, in turn, has allowed Amgen to increase the prices paid by its customers in order to continually increase its sales and the profits realized by both Amgen and its customers for Amgen's drugs.

57. This "competitive" environment has not benefited the Government Plaintiffs, patients or taxpayers. Instead, it has had the opposite effect. By "competing" on spreads, Amgen has caused the Government Plaintiffs and taxpayers to pay more for Amgen's drugs than they otherwise would have paid in the absence of Amgen's misconduct. Amgen knows that the profit or "spread" on drug utilization introduces an incentive for physicians and providers to prescribe and use more of the product than they otherwise would, which also increases the costs to the Government Plaintiffs and other payors.

58. Amgen also knew that several of its drugs compete with other manufacturers' drugs. In some cases, as detailed herein, Amgen manipulated the AWP to create a reimbursement advantage for its drugs. Specifically, Neupogen and Neulasta

competed against Immunex's Leukine; and Aranesp competes against Procrit, Johnson & Johnson's epoetin alfa product. In order to assure that its drugs gained market share, Amgen further engaged in AWP manipulation so that reimbursement rates would be higher for its drugs.

59. To implement its scheme, Amgen trained its sales representatives to focus on reimbursement and customer profit motives and provided sales representative with marketing tools such as cost calculators to support this scheme.

60. Amgen contracts were structured in such a way as to provide increasing discounts based upon increasing dollar purchases of Amgen products. Additional prescriptions of Amgen products caused the price paid by customers to decrease, and the "spread" between reimbursement and cost to increase. Thus, a provider's profitability increased with greater utilization of Amgen product. Amgen helped customers to understand the economic benefits to greater utilization of their products, including providing target patient utilization numbers for each increasing level of product discount.

61. Recommending patient utilization based upon financial targets runs counter to the concept of medical necessity and encourages product usage for financial gain rather than for medical necessity. For example, Amgen had offered an Enhanced Physician Office Agreement Rebate Schedule for Aranesp and Neulasta for the 2002/2003 fiscal year. Under this program, a sliding scale of rebates from Amgen was based on the net purchases of these drugs by physicians. Rather than basing product usage on medical necessity, this program encouraged the utilization of the drugs to be based on financial targets.

62. By way of further example, consider that since the release of Aranesp in October of 2001, the competitive environment between Amgen's Aranesp and Ortho

Biotech's Procrit has changed several times. Because of changing government reimbursement levels, and changing contracts responding to both reimbursement changes and competitive contract levels, the "spread" advantage has vacillated back and forth between Aranesp and Procrit over this entire time period.

63. Because Amgen was convinced its competitor Ortho Biotech was marketing Procrit using the spread or profit during the time frames that it had an advantage, Amgen sales representatives were advised to gather any and all evidence that they could, to demonstrate to the federal government that Ortho Biotech was marketing on the spread.

64. Conversely, when the spread advantage was in Amgen's favor, Amgen management cautioned the Amgen sales force that Ortho would be looking for any evidence that they could find to show the government that Amgen was marketing on the spread.

65. Therefore, when Amgen had the advantage on profit, sales representatives were advised by management to "be smart---use it, but don't leave it. ["it" being spread marketing tools]" On the other hand, when Ortho had the profit advantage, Amgen representatives had no incentive to market the "spread" and instead shifted to a cost reduction marketing strategy. This dynamic has shifted several times since the introduction of Aranesp.

66. At most regional and district meetings attended by relator Arriazola, managers made presentations as to the current economic competitive environment between Aranesp and Procrit. Her fellow representatives also discussed and made presentations on various marketing techniques employed to increase sales, including marketing the spread. The regional and district managers implicitly condoned these schemes, as they expected their representatives to use the sales techniques discussed at these meetings.

67. Relator Arriazola was provided with spreadsheets and cost calculators by her managers to discuss with her customers. These materials laid out what potential profits could be made by the customers through purchases of Amgen products. However, in order to preclude competitors and/or regulators from obtaining evidence of marketing the spread, Arriazola was directed to retain these materials rather than leaving them with her customers.

A. HOSPITAL CONTRACTS PURSUANT TO WHICH AMGEN PROMOTED THE "SPREAD" ILLEGALLY GENERATED BY AMGEN.

68. Defendant Amgen also entered into improper contracts with private and public hospitals. The improper contracts included various improper inducements, including rebates and discounts, designed to increase Amgen's market share of specific products and to increase its overall volume of sales. These inducements were made to encourage Amgen customers to prescribe and sell Amgen's drugs over competing drugs or alternative forms of medical care and treatment, not to ensure that the most medically appropriate treatment was provided.

1. The Enhanced Momentum II Hospital Contract.

69. Due to the ongoing competitive marketing of Aranesp and Ortho Biotech's Procrit, Amgen developed the Momentum I hospital contract in 2003 to counter the pricing and marketing schemes of Procrit. Due to revised pricing schemes for Procrit and Aranesp, the Enhanced Momentum II Hospital Contract (Momentum II) was developed and took effect for the period of June 1, 2004 through April 30, 2006. Hospitals that were already purchasing Neulasta and Neupogen were automatically enrolled in this program.

70. Under the terms of the contracts, the hospitals receive off-invoice discounts of 25% on their purchases of Aranesp vials and singlejects and 2% off the purchases of Neulasta and Neupogen.

71. Hospital-based dialysis centers receive an off-invoice discount of 11% on all Epogen vials, with the exception of Epogen M20 vials for which an off-invoice discount of 17% is provided. Hospitals without dialysis centers receive a discount of 3% on all Epogen vials.

72. Further, effective October 1, 2004, pursuant to the Momentum II contract, hospitals also receive unreported rebates from Amgen based on the market share of Aranesp and volume of sales of Neulasta and Neupogen.

73. The hospitals receive rebates of up to 21.5% on their total quarterly purchases of Aranesp based on this drug's market share at the hospital. The hospitals also receive rebates of up to 8% on their quarterly purchases of Neupogena and Neulasta, with the rebate amounts directly tied to Aranesp's market share.

74. To receive the rebate on the purchases of Neulasta and Neupogen, the hospital's net quarterly purchases have to equal or be greater than 70% of the prior year's same-quarter net purchases.

75. By offering these increased off invoice discounts and rebates based on the market share of Aranesp and continued high purchase volumes of Neulasta and Neupogen, Amgen improperly induced the hospitals to prescribe and sell Amgen's drugs over competing drugs or alternative forms of medical care and treatment. The scheme interfered with the healthcare provider's ability to make unbiased and neutral judgments as to the appropriate medicines to use. As a result, the Government Plaintiffs have been harmed by Amgen's conduct.

2. *The Total Oncology Partner Program*

76. Amgen also initiated the Total Oncology Partner program ("TOP") with many of the same hospitals that were participants in the Momentum II contract. The TOP program similarly also offered illegal inducements to participant hospitals in the form of rebates in two ways.

77. The TOP program offered rebates to hospitals based on Amgen's increase in product market share at individual hospitals. If Amgen's product market share increased by 1.5 % to 9.49% in a given quarter, the hospital received a rebate of 21.5% on its Aranesp purchases and a rebate of 2% to 4% on its purchases of Neulasta and Neupogen.

78. If Amgen's quarterly product market share at the hospital reached at least 79.5% or the market share had increased by 9.5% or more in the quarter, the hospital receives a rebate of 21.5% on Aranesp and a rebate of 7% on the purchases of Neulasta and Neupogen.

79. Further, if the hospital was a partner in both the Momentum II and TOP programs, it was entitled to combine its rebate percentages for its eligible Neulasta and Neupogen purchases.

80. For example, if the hospital achieved the top tier rebate percentage of 7% for Neulasta and Neupogen under Momentum II and the top tier rebate percentage of 8% under the TOP program, the rebate paid by Amgen was increased to 15% of the purchases of these drugs.

81. By tying together the two programs and offering increased rebates based on the level of Amgen's market share, this scheme interfered with the hospitals' ability to make unbiased and neutral professional judgments as to the appropriate medicines to prescribe for the care of its patients.

82. By offering these increased off invoice discounts and rebates based on the market share of Aranesp and purchase volumes of Neulasta and Neupogen, Amgen improperly induced the hospitals to prescribe and sell Amgen's drugs over competing drugs or alternative forms of medical care and treatment. As a result, the Government Plaintiffs have been harmed by Amgen's conduct.

3. The APC Contract

83. Amgen's contract applicable to physician clinics was the APC contract, otherwise known as the Amgen Physician Contract, Amgen Product Contract or Amgen Portfolio Contract.

84. The contract provided for similar off-invoice discounts and rebates on Amgen products as the Momentum and TOP contracts however, the APC contract was tailored to physician clinics. Also like TOP and Momentum, the rebates and off-invoice discounts were tiered, and increased as customer's purchases of Aranesp, Neupogen and Neulasta increased.

85. Examples of clinics which purchased Amgen products subject to the APC contract include the Mayo Clinic, Matthews Oncology Associates, Sheboygan Clinic, South Carolina Oncology Associates, and Hematology-Oncology of Central New Jersey.

86. With Aranesp, Amgen has supported increasing the market share of product used in the retail setting, because greater retail prescriptions will have a net effect of raising the ASP that Medicare began to use to set reimbursement of drugs in 2005 and beyond. Amgen does not grant price concessions to retail pharmacies, but gives large discounts to hospitals and physicians; therefore, higher sales in the retail setting will tend to raise the ASP. To support this strategy, Amgen has offered a significant bonus to all sales

representatives who can increase their retail market share during the last half of 2004. Amgen's scheme is aimed at converting retail prescriptions of Procrit to retail prescriptions of Aranesp, thus increasing the ASP for Aranesp, while decreasing the ASP of Procrit. Influencing the ASP of both products in those ways plays into the overall strategy of offering superior financial incentives to providers through the "spread."

87. Indeed, among the measure taken by Amgen to increase the ASP for Aranesp so as to increase the spread was a voucher rebate program, launched in mid-2004 in preparation for the switch to an ASP-based reimbursement schematic for government-funded healthcare programs in 2005. Once the ASP-based reimbursement schematic was set to be implemented, Amgen began to consider the retail market to be a "[s]trategically important market segment."

88. Pursuant to the voucher program, Amgen sales representatives were given vouchers for a free month's supply of Aranesp to distribute to targeted physicians to encourage Aranesp prescription writing. In turn physicians were to give these vouchers to their patients. The vouchers came in the form of a special retail label that the physician would affix to his or her Aranesp prescription. The special label "enrolled" the patient so he or she was eligible to receive free Aranesp. The patient would take the prescription affixed with the special label and collect his or her free on month supply of Aranesp at the pharmacy. The free month's supply was offered in the following doses only: 4/100 mcg pre-filled syringes or 2/200 mcg pre-filled syringes.

89. Amgen intended that the free one month supply of Aranesp would lead to refill prescriptions paid at full price thereafter from the retail pharmacies. Subsequent refills would follow the standard prescription refill process and the appropriate cost would be

charged to the patient's non-government-funded prescription plan as well as the necessary co-pay.

90. Amgen expressly excluded from the voucher program all patients who participated in Medicare, Medicaid or other federal or state health programs

91. In furtherance of the roll out of the voucher program, Amgen provided sales representatives with retail target lists as well as Aranesp sample kits equal to the number of top retail targets in each representative's territory.

92. Amgen put no limit on the number of patients a physician could enroll in the voucher program.

93. The purpose of the voucher program was to drive retail sales of Aranesp, with the ultimate goal of increasing Aranesp's ASP, and in turn with the effect increasing the spread for physician customers who were afforded deep discounts below the ASP price. Indeed, Amgen stated that retail sales were of "increasing importance" in 2005.

94. Upon information and belief, for the purpose of artificially inflating the ASP for Aranesp, Amgen purposefully did not take into account the voucher program discounts in calculating ASP or in calculating best price/AMP.

95. Amgen amended its APC contract to support the retail voucher effort and its scheme to inflate ASP. Specifically, on April 15, 2004, Amgen notified its APC customers via letter that effective May 1, 2004, Amgen would implement changes to the APC contract with respect to the volume purchase requirements set forth in the APC. Effective May 1, 2004, the volume purchase requirements of Aranesp, Neulasta and Neupogen required to be reached to earn rebates under the APC were modified to include Physician Practice retail pharmacy prescriptions measured using the [prevailing Wholesaler Acquisition Price in

effect at the time the prescription was filled, excluding all federally-funded healthcare programs such as Medicare.

96. Amgen revised its APC contract in this was because retail prescriptions were critical to inflating ASP, which was fundamental to Amgen's marketing the spread schemes. Moreover, the roll out of this highly significant modification to the APC contract coincided with the roll out of a voucher rebate program.

97. By offering these increased off invoice discounts and rebates based on the market share of Aranesp and purchase volumes of Neulasta and Neupogen, Amgen improperly induced physician clinics to prescribe and sell Amgen's drugs over competing drugs or alternative forms of medical care and treatment. As a result, the Government Plaintiffs have been harmed by Amgen's conduct.

4. The Disproportionate Share Program

98. In April 2004, Amgen initiated the Disproportionate Share Program (Dsh). That program is a contractually based program directed to public hospitals, notably, those PHS-eligible public hospitals which have a disproportionate share of indigent patients. The program contained illegal inducements, including high off-invoice discounts that were designed to attract and retain business from these entities.

99. This two-tier program was offered to hospitals meeting certain criteria. If the hospital had a 50 % market share of Aranesp products for the two months prior to executing a Letter of Commitment (LOC) and its purchases of Neulasta and Neupogen for the quarter prior to executing the LOC was equal to or greater than 70% of its purchases for the prior year's same quarter, it was enrolled in the Dsh Program A. If the hospital met only the Aranesp criteria, it was enrolled in the Program B Option. The hospital also agreed to waive

any discounts, rebates or other incentives it was receiving under any group purchasing organization (GPO) agreement. The Dsh program offered substantially higher off-invoice discounts off the prevailing Wholesaler Acquisition Price for its inpatient pharmaceutical purchases as opposed to the GPO agreements.

100. If a hospital was to commit to a planned therapeutic exchange from Procrit to Aranesp, Amgen would waive the program enrollment requirements provided that the exchange occurred within 60 days of execution of the Letter of Commitment and the hospital achieved the 50% Aranesp market share level within 60 days of participation in the Dsh program.

101. Hospitals in the Dsh Program A receive discounts of 38.4% to 42.25% on certain Aranesp products, an 8% discount on certain Neupogen products, 10% on certain Neulasta products and 3% on Epogen. The hospital remains eligible for these discounts as long as it meets and maintains a 50% Aranesp market share on a monthly basis and the hospital's Neupogen and Neulasta purchases during any given calendar quarter are greater than or equal to 70% of the hospital's purchases during the prior year's same calendar quarter.

102. If the hospital enrolls in the Dsh program B option, the hospital receives the Program A discounts on the Aranesp and Epogen products, while the hospital's discounts were reduced to 2% for its Neupogen and Neulasta purchases

103. If a "Program A" hospital maintains its Aranesp goal but fails to meet the Neulasta/ Neupogen goal in any given quarter, the hospital is transferred to the Program B Discount option. Further, if a Program A hospital fails to maintain its Aranesp market share levels for 3 consecutive months, regardless of whether it met the Neulasta/Neupogen goals

for the quarter preceding the last month of Aranesp noncompliance, it is terminated from the Dsh program and realigned with its prior GPO Agreement under which it was purchasing Amgen products.

104. If a hospital enrolled in the Program B discount plan fails to meet its Aranesp 50% market share goal for three consecutive months, it is terminated from the Dsh program and realigned with its prior GPO Agreement under which it was purchasing Amgen products.

105. The discounts under the Dsh program were substantially higher than those available under GPO agreements. By using a "carrot" (significant discounts available through enrollment in the Dsh program) and a "stick" (removal from the program if the volumes of Amgen products purchases did not meet the required purchasing tiers), Amgen was able to increase the market share for its drugs and drug revenues by inducing hospitals to achieve and maintain high levels of purchases from Amgen.

106. More importantly, by undercutting the recent pricing schemes of Ortho Biotech, and waiving pre-enrollment requirements for healthcare providers using Procrit, Amgen induced healthcare providers to switch over to Aranesp as they received substantial price breaks on the various Amgen products.

107. By offering these increased off invoice discounts based on the market share of Aranesp and continued high purchase volumes of Neulasta and Neupogen, Amgen improperly induced the hospitals to prescribe and sell Amgen's drugs over competing drugs or alternative forms of medical care and treatment. The scheme interfered with the healthcare provider's ability to make unbiased and neutral judgments as to the appropriate

medicines to use. As a result, the Government Plaintiffs have been harmed by Amgen's conduct.

B. IMPROPER PAYMENTS TO CONSULTANTS TO INFLUENCE HOSPITALS

108. Amgen retained paid consultants to meet with the appropriate parties at private and public hospitals to persuade the hospitals to switch to and/or increase their volume of purchases of Amgen products. In most hospitals, the appropriate parties to speak with would be the director of the pharmacy and other senior medical staff.

109. Amgen determined that the directors of pharmacy at the large academic and institutional hospitals were the key persons to contact as they made the critical decision as to what drugs were put on formulary. Amgen used its paid consultants to meet with and discuss the clinical and economic advantages of using Amgen products over those of its competitors.

110. By way of example, Relator Arriazola has personal knowledge that such an activity took place in the spring of 2004. Amgen's Dsh Program had recently been launched. Among those which Amgen wished to contract with was the University of Chicago Hospital, Chicago, Illinois.

111. Amgen retained Jim Stephenson, who was a pharmacist at the University of Michigan. Stephenson, along with Amgen's regional and district sales managers, met with the Chief Financial Officer, the Director of Pharmacy, and an Oncology Pharmacy Specialist of the University of Chicago Hospital, to discuss a larger commitment to the purchase of Amgen products, the DSH program discounts, and the competitive pricing scheme of Aranesp over its chief competitors.

112. Shortly after this meeting, on April 12, 2003, the University of Chicago agreed to enroll in the Dsh program.

113. Stephenson has also been retained by Amgen to make similar presentations at other PHS eligible hospitals throughout the country. Through use of the paid speakers, Amgen's goal has been to enroll as many PHS eligible hospitals into the Dsh program as possible. These enrollments are largely due to the illegal inducements offered in the Dsh program utilizing Amgen products. Stephenson's status as paid consultant was not revealed to the potential customers he solicited on behalf of Amgen.

114. Amgen paid for the expenses related to Stephenson's marketing efforts at the University of Chicago and elsewhere throughout the country. The objective of these presentations was to show the clinical and financial benefits of using Amgen products. These presentations were intended to provide an illegal inducement to the hospitals to change or switch their prescribing and billing habits in order to create financial incentives for greater Amgen product use.

C. IMPROPER USE OF PROFESSIONAL ADVISORY BOARDS TO INFLUENCE HOSPITALS AND OTHERS.

115. Amgen participated in other activities to induce hospitals, doctors and other healthcare providers to promote the sale of their products and/or switching to its products at substantially discounted prices.

116. Amgen retains so-called Professional Advisory Boards (PABs) that generally consist of doctors who have favorable opinions of Amgen products. The purpose of these boards is to discuss and advocate the use of Amgen products at seminars and other medical professional gatherings. In other words, PABs are simply yet another marketing

tool in Amgen's arsenal as well as way to disguise bribes to high volume Amgen drug prescribers to maintain their loyalty to Amgen products.

117. The PAB presentations are directed to medical professionals who are ambivalent about the use of Amgen products and/or who strongly prefer products of Amgen's competitors, including, but not limited to, Ortho Biotech's Procrit.

118. The PAB members extol the benefits of Amgen products and relate anecdotes of their successes with Aranesp and other Amgen pharmaceuticals. Their efforts are geared to convincing their audience to either increase their use of Amgen product or to switch over from the use of the competing products.

119. All of the seminar attendees receive a stipend from Amgen and the PAB members receive a fee and partial reimbursement of their expenses from Amgen. The payment of the fees create an inherent conflict of interest and led to biased opinions of the PAB members, as their presentations favor Amgen over its competitors and the seminar attendees are not made aware of the financial dealings between the speakers and Amgen

120. Similarly, Amgen had a Pharmacy Advisory Board (PhAB), whose purpose was to advise pharmacists, particularly those at hospitals and other large institutions, as to the economic and clinical benefits of using Amgen products. Directors of pharmacies at large hospitals were the key contact persons, from Amgen's perspective, as they generally controlled what drugs went on formulary.

121. While employed as a HSM, Plaintiff Arriazola obtained information that the director of pharmacy for the University of Chicago Hospital received an expenses-paid trip to Miami, Florida to a PhAB meeting in the spring of 2004. This trip occurred at the same

time the Dsh program was rolled out and the University of Chicago Hospital was a sought-after customer.

122. Amgen's payment of the expenses of this person was an illegal inducement for the University of Chicago Hospital to change or switch their prescribing habit and was a financial incentive for the greater use of Amgen products.

D. IMPROPER USE OF UNRESTRICTED EDUCATIONAL GRANTS TO INFLUENCE HOSPITALS AND OTHERS

123. In an effort to increase its volume of sales with existing customers, namely, hospitals, Amgen would make what were known as unrestricted educational grants to various physicians, hospitals, and other institutions. These grants would often be in the form of a sponsorship of a seminar or meeting held at existing or potential customer facilities. The sponsored speaker(s) would discuss disease processes and stages and further discuss how Amgen products were clinically and economically beneficial in the treatment of these diseases.

124. Although Amgen would provide lip service in letters and other materials related to grants of this nature that there was no expectation of any quid pro quo, there was an implicit understanding that the grantee would increase its purchases of Amgen product and/or its speakers would advocate the use of the Defendant's products to other attendees at the seminar.

125. By way of example, in January 2005, Amgen was asked to make such a grant to Rush University Medical Center for its 5th Annual Rush Review. Various seminars were planned to discuss synopses of the latest clinically relevant research. Amgen provided a grant in the amount of $10,000 in support of this seminar and there was an unspoken expectation that the hospital would increase its purchases of Amgen products and/or

speakers at the seminar would comment favorably on the Defendant's products, including Aranesp.

126. These grants were illegal inducements to the hospitals to change or switch their prescribing and billing habits in order to create financial incentives for greater Amgen product use.

E. IMPROPER USE OF PATIENT EDUCATION GRANTS TO INFLUENCE HOSPITALS AND OTHERS

127. In addition to the unregistered education grants, Amgen would also supply what were known as Patient Education Grants ("PEGs").

128. These grants were made to various hospitals for the purchase of various education materials and other supplies a hospital needed to create a patient education center. These materials would consist, in part, of books, and research materials on cancer and the various treatments.

129. In exchange for providing funds for these centers or rooms, the hospitals were expected to increase or maintain its purchase of Amgen pharmaceutical products. This was an implicit understanding as Amgen was careful not to state its expectations in any correspondence related to these grants.

130. For example, in 2005, the University of Illinois Medical Center received a PEG in the amount of $5,000.00 from Amgen to establish such a center.

131. These grants were illegal inducements to the hospitals to change or switch their prescribing and billing habits in order to create financial incentives for greater Amgen product use.

VII. OTHER IMPROPER MARKETING SCHEMES

A. IMPROPER "IN OFFICE" SCHEME

132. Plaintiff Arriazola further alleges that Amgen, in full knowledge of government prohibitions for reimbursement of self-administered drugs, has created a scheme whereby the Government Plaintiffs paid for self-administered drugs under the "incident to physician care" regulations, with full knowledge that these products can be safely and effectively administered by the patient.

133. For example, Amgen's Neulasta is provided in single dose, prefilled syringes. The FDA labeling requires no additional patient testing or intervention after administration. In furtherance of its schemes, Amgen instructed its sales representatives *not* to volunteer any information to medical providers and other purchasers about the fact that administration of Neulasta does not require physician assistance. Physicians would be able to bill the government or private insurers if they, rather than the patient, administered the drugs and therefore would make a substantial profit for this procedure.

134. These improper marketing and sales schemes were formulated as part of an overall plan by Amgen to engage in unlawful and improper methods of competition in the marketing and sale of its drugs to the detriment of the Government Plaintiffs.

135. The goal of this unlawful marketing and sales scheme is to cause Amgen's drugs to be favored by medical providers and other purchasers above all other drug therapies and modes or methods of healthcare treatment for particular health conditions. This goal is achieved by improperly persuading medical providers and other purchasers of the Amgen products at issue to administer these drugs "in office" which allows medical providers to

profit from administering these drugs and benefits Amgen in the form of artificial inflation in market share.

B. AMGEN'S IMPROPER "IN CLINIC" SCHEME

136. In carrying out its schemes, Amgen representatives advised integrated healthcare institutions as to what site of service was the most profitable for their patients, suggesting that hospital outpatient centers direct the provision of Amgen products (Neupogen, Neulasta and Aranesp) to their associated clinics, because the government reimbursement rates were higher in the clinic settings, and the customers could thereby increase the "spread" that was realized on the provision of the products.

137. This activity occurred after the institution of the first Outpatient Prospective Payment System (OPPS) by Medicare, in which hospital outpatient reimbursement was set by Medicare at a different rate than in the physician clinic setting. The details of the new OPPS rule were made public in October 2002.

138. Amgen's recommendation to customers that they transfer patients from their traditional site of service to a different, more costly site of service caused Medicare and other government-funded healthcare programs to incur greater treatment costs. This recommendation, in conjunction with the promotion of drug profit or spread, and the differential profit in different treatment settings, constituted an illegal inducement with the net effect of making it more attractive for physicians and health systems to use more of Amgen's products.

139. Moreover, Amgen is well aware that their injectable products Aranesp and Neulasta were and are at risk of being declared self-administered drugs. Removing Medicare coverage from either of these products would diminish the profit incentives that

Amgen has devised as a part of their highly successful promotion of these products. Therefore, Amgen carefully monitors and calibrates the amount of self-administration that is occurring with each of their injectable drugs. Self-administered product is usually purchased by retail pharmacies for dispensing to patients who receive a prescription from their physician.

140. With Aranesp, Amgen is supporting increasing the market share of product used in the retail setting, because greater retail prescriptions will have a net effect of raising the Average Selling Price ("ASP") that Medicare began using to set reimbursement of drugs in 2005 and beyond. Amgen does not grant price concessions to retail pharmacies, but gives large discounts to hospitals and physicians; therefore, higher sales in the retail settings will tend to raise the ASP.

141. Amgen's scheme is aimed at converting retail prescriptions of Procrit to retail prescriptions of Aranesp, thus increasing the ASP for Aranesp, while decreasing the ASP of Procrit. *Influencing the ASP of both products in those ways plays into the overall strategy of offering superior financial incentives to providers through the "spread."*

VIII. ILLEGAL OFF-LABEL MARKETING

142. From 1998 through 2005, Pam Arriazola worked as a pharmaceutical sales representatives and health systems manager in the state of Illinois. During that time, she marketed Aranesp, Neupogen, Neulasta and Kepivance to community hospitals, physician practice groups and academic/teaching hospitals.

A. FDA REQUIREMENTS FOR DRUG ADVERTISING AND LABELING INFORMATION

143. The pharmaceutical industry is highly regulated by the Food and Drug Administration ("FDA").

144. Pursuant to the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, the FDA strictly regulates the content of consumer and physician based advertising, direct to physician product promotion, and drug labeling information used by pharmaceutical companies in promoting and selling FDA approved prescription drugs.

145. Under 21 C.F.R. § 202.1(k) (2), any brochures, handouts, slide shows or other such promotional materials aimed at physicians are deemed to be "product labeling" and is regulated as such.

146. Under relevant FDA regulations, product labeling must be pre-approved by the FDA and conform to very exacting requirements concerning, *inter alia*, drug interactions, indicated uses and claims concerning competing products. *See* 21 C.F.R. § 201.57.

147. All claims made in any labeling material must be truthful, not misleading and represent a fair balance of the information presented.

148. Any presentations, promotions, or marketing to physicians for products for use other than that approved for labeling purposes by the FDA is considered "off label" marketing and is thus prohibited by FDA regulation.

149. Any failure to represent fairly and accurately the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. *See* 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

150. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading violate the Food Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated hereunder. Such

violations exist where promotional and marketing materials and presentations for an FDA approved drug:

- Minimize, understate or misrepresent the risks, contra-indications and complications associated with that drug;
- Overstate or misrepresent the risks, contra-indications and complications associated with any competing drugs;
- Reference "off label" uses of the drug for which it was not an approved indication by the FDA, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated;
- Make comparative claims about the drug that have not been demonstrated by substantial evidence, such as comparisons with competing drugs and/or drug indications of patient usage, warnings and safety claims including side effects, physician preference, or
- are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

B. AMGEN'S OFF-LABEL MARKETING SCHEMES

151. Amgen currently markets Epogen, Aranesp, Neupogen, Enbrel, Kineret, Kepiance and Neulasta. The FDA has approved each of these medications only for the treatment of specific medical conditions.

152. Amgen has engaged in a pattern of marketing each of these medications for "off-label" uses not approved by the FDA. Arriazola, during her tenure with Amgen become familiar with the "off-label" promotional schemes involving Aranesp and Neulasta. Relator Arriazola believes that these schemes are ongoing.

153. In order to effectuate its off-label marketing program Amgen has engaged in a scheme to make unsubstantiated representations as to the efficacy of certain of its medications.

1. Aranesp

154. On or about September 17, 2001, the FDA approved Aranesp for use in the United States for the treatment of anemia associated with chronic renal failure (both in

patients on dialysis and those not on dialysis). On or about July 17, 2002, the FDA approved the drug for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies.

155. Aranesp FDA-approved dosing regimens for Aranesp are disease specific, with a recommended starting dose in renal failure patients of .45mcg/kg body weight injected on a weekly basis. For patients with chemotherapy induced anemia, the recommended starting dose is 2.25 mcg/kg administered as a weekly subcutaneous injection. Accordingly, the only on-label dosage is once weekly.

156. Off-label promotional activities with Aranesp have occurred and been encouraged from the original approval date, despite stated company policy of not engaging in off-label promotion.

157. The various off-label promotional schemes engaged in by Amgen relative to Aranesp include:

- Promotion of various off-label dosing schemes, including once every two weeks (Q2W), once every 3 weeks (Q3W)[1] and monthly dosing in oncology patients. Also, Q2W, Q3W and once per month dosing in renal patients;
- Promotion of use of Aranesp in the Anemia of Cancer (AOC), also referred to as the Anemia of Malignancy; and,
- Promotion of the use of Aranesp in Myelodysplastic Syndrome, or MDS.

158. Amgen's sales support for promotion of these off-label indications has included training materials and presentations on both a national and regional level, provision

[1] The FDA approved Q3W dosing of Aranesp in the treatment of CIA only on March 23, 2006. Therefore all of Amgen's marketing for Aranesp Q3W in CIA prior to that date and all marketing of Q3W in CRF patients was and was off-label and caused false Aranesp claims to be submitted to government-funded healthcare programs such as Medicare and Medicaid. In addition, Q2W dosing was off-label at all relevant times for CIA patients.

of a "proof source" book with abstracts and posters, representative "personal selling binders" composed of FDA approved literature commingled with personally selected, and sometimes personally produced, selling materials, and non-branded discussion aids to discuss a non-indicated disease state (AOC).

159. Additional support included the activities of the Government Economic Managers who were actively lobbying Medicare to cover the various off-label indications and schemes, as physicians would not prescribe medications that would not be reimbursed.

a. Anemia of Cancer

160. Because Amgen knew that the off-label uses for which it was promoting its drugs were not eligible for reimbursement under government-funded health care programs, including Medicaid, Medicare, Medicare Part B, Medicare Part D, Tri-Care/CHAMPUS, ChampVA and others as described herein, in furtherance of its "spread" and off-label marketing programs, Amgen engaged in an active campaign, through direct promotional efforts, to convince its end-customers to lobby the Center for Medicare and Medicaid Services and local Medicare Carriers for reimbursement of off-label uses of Amgen products, including Anemia of Cancer.

161. The general restrictions on reimbursement of prescription drugs by government-funded health care programs is set forth *supra*. However, Congress provided that local Medicare Medical Directors can approve reimbursement of off-label uses where the product can be shown to be safe and effective by independent, peer reviewed literature. In furtherance of this activity, Plaintiff Arriazola was directed by her sales managers to ask her customers to write letters requesting that off-label uses of Aranesp and Neulasta be reimbursable under the government-funded healthcare programs.

162. Amgen's successful but improper attempts to influence Medicare Carriers and Fiscal Intermediaries to expand coverage to include off-label indications bestows a huge financial benefit on Amgen by allowing the company to avoid the lengthy and incredibly costly process of seeking approval of new uses.

163. By convincing customers to lobby for government reimbursement, Amgen is aware that physicians will be unencumbered by the financial constraints of lack of reimbursement, and be free to increase prescriptions for off-label uses. An example of this promotional scheme occurred in November and December of 2003 regarding the product Aranesp, and the un-approved indication of Anemia of Cancer. Amgen pursued a strategy whereby they applied for inclusion of the AOC indication by the USP-DI (a division of Thomson Micromedex).

164. Despite the lack of any published clinical trials on Aranesp's safety or efficacy to treat AOC, the USP-DI designated AOC as "accepted" in November of 2003. On December 6, 2003, a single abstract (author Charu, et al) was presented at the American Society of Hematology, and published in the ASH journal Blood.

165. Relator Arriazola and other Amgen representatives participated in subsequent sales meetings, and in, preparation for the same, and at the meeting itself, Amgen representatives were educated about AOC and the Charu data. Representatives were provided copies of the Charu ASH poster and abstract for inclusion in their "proof source" book. They were also provided with a "non-branded disease state" detail piece that discussed the incidence and features of AOC at several sales training sessions. Amgen also paid for the participation of existing customers (physicians, pharmacists) in role-playing

exercises so that the sales representatives could learn what the medical professionals wanted to hear about the products and their clinical and economic benefits, including off-label uses.

166. Amgen representatives were instructed to use the non-branded AOC detail piece to initiate a discussion of the AOC disease state with the customer designed to elicit an "unsolicited question" from the customer regarding the use of Aranesp in AOC at which time the sales reps would use the Charu data to demonstrate the effectiveness and benefits of this off-label use of Aranesp in this patient population. Representatives were also instructed to inform physicians that Aranesp was compendium listed for AOC, to provide copies of the USP-DI compendium listing, and to ask the physician to contact the local Medicare Medical Director to ask for Medicare coverage of Aranesp for AOC (and other off-label uses, such as Q2W and Q3W). Representatives were provided with contact information for their respective Medicare Medical Directors so that they could facilitate physicians in making such requests to Medicare. By 2005, most Medicare contractors covered Aranesp when prescribed to treat AOC.

167. By expanding the reimbursement coverage for Aranesp in this way, the market for this class of drugs increased dramatically. A conservative estimate would be a potential increase in usage of product by one third. In that the market for this drug class results in US sales of over $3 Billion dollars per year, most of which is covered by Medicare and Government payment programs, this increase in coverage will result in significant additional expenditures by Medicare, based upon a very small threshold of proof.

168. The inherent danger to patients of pharmaceutical companies engaging in short cuts to circumvent the FDA-approval process for the sole purpose of increasing revenues became clear with regard to Aranesp in January 2007. On January 25, 2007,

Amgen announced the results of a large scale, placebo-controlled trial of Aranesp in the Anemia of Cancer. Amgen initiated this study to substantiate Aranesp's safety and efficacy in the off-label AOC use and for the purpose of applying for an FDA indication for the Anemia of Cancer.

169. Instead, Amgen was forced to reveal that the results of the trial showed that Aranesp was ineffective in treating AOC.

170. Even worse, however, the trial showed a ***statistically significant increase in the rate of death of patients treated with Aranesp relative to placebo when used to treat anemia of cancer***. This trial was a phase 3, double blind placebo controlled trial, which is the gold standard for all drug trials. In addition, this trial involved a sufficient number of participant patients to confirm statistically a difference between the treatment and the control groups with regard to outcomes.

171. This trial -- which Amgen irresponsibly failed to conduct prior to launching its off-label AOC marketing campaign for its blockbuster drug - also proved that for years, while Amgen's profits were increasing from Aranesp sales for AOC, the lives of patients with cancer were placed in even graver danger than that posed by the disease itself.

172. The trial, which should have been done prior to any promotional activity by Amgen regarding usage of Aranesp in the Anemia of Cancer, actually disproved the results of the Charu pilot study that was used to support the off-label promotional activities that led to Medicare coverage.

173. In response, in 2007, the FDA posted an alert on MedWatch, which is the FDA's safety information and adverse-event reporting program. The alert identified the study and flagged the increased risk of death and the product's ineffectiveness in reducing

red blood cell transfusions and adds that it failed to reduce fatigue as well. Subsequently, the FDA required Amgen to place a black box warning on the Aranesp label warning, and thereafter to expand the scope of the black box warning. By 2008, the black box warned of the increased risk of death and lack of efficacy when Aranesp is used off-label, i.e. to treat Anemia of Cancer, and specified that Aranesp should only be used on-label in the lowest effective dose to treat chemotherapy-induced anemia.

b. Off-label Promotion for Extended Dosing and MDS

174. After successful changes in the reimbursement policies for the unapproved indication of Anemia of Cancer/Anemia of Malignancy, Amgen pursued the same course of action to attempt to achieve Medicare coverage of MDS.

175. MDS disorder is a precancerous condition that disrupts the normal production of red and white blood cells, leading to low blood cell counts of both types of cells (anemia and neutropenia). MDS is a slowly progressing disease and is mostly intractable to treatment. It is considered a precancerous condition because it can transform into Acute Myelogenous Leukemia ("AML"). During the MDS stage, patients receive blood transfusions as needed to treat the anemic symptoms. While erythropoiesis stimulating proteins ("ESPs") such as Procrit and Aranesp have been tried in this population, treatment has been only marginally effective, and therefore, the FDA has no approved Aranesp – or Procrit – for use to treat anemia in this patient population.

176. Because of equivocal effectiveness, Medicare regulations allowed only a temporary trial of Procrit, with demonstration of effectiveness on a patient by patient basis for coverage to continue.

177. Accordingly, Amgen was interested in broadening the reimbursement rules

to allow physicians to treat anemia of MDS without the burdensome restrictions on physician prescribing behavior.

178. During 2005, Amgen Hospital System Managers, including Plaintiff Arriazola, as well as Oncology PSRs were provided with information on the use of Aranesp for MDS in the form of abstracts or reprints included in their "Proof Source" materials. These reprints included Glaspy (Q2W), Thames (Q2W), Boccia (Q3W) and Schwartzberg (Q2W). Representatives were authorized to use these materials in response to "specific unsolicited" questions from physicians, but in reality, it was expected by sales management that these materials would be presented at almost every physician meeting in response to the question, "What's new?"

179. Proof Source materials were provided to sales representatives in January 2005 in the Semester 1 sales materials, in July of 2005 in the Semester 2 materials, and in October of 2005 in the Semester 3 materials. Presentation of the clinical data on AOC, MDS and approved indications was to be coupled with regular presentation of the Amgen Portfolio Contract and the Momentum and TOP contracts, and their associated product economics, meaning rebate potential and physician profit. This was due to the fact that usage of Aranesp in MDS would help physicians to meet their purchase goals for the various clinic and hospital contracts, and provide higher rebates and levels of profitability for the physician offices.

180. Another method orchestrated by Amgen to market Aranesp off-label for MDs – and for AOC – was for sales representatives to bring a Pharm. D employed by Amgen as a medical Science Liaison along during sales calls to deliver the off-label sales pitch. Accordingly, Plaintiff Arriazola witnessed Amgen PharmD Bill Wagley routinely

promote Aranesp off-label for MDS and AOC.

181. In addition, representatives, including Plaintiff Arriazola, were told to encourage physicians to write letters of request to the Medicare Carrier Medical Directors requesting coverage of MDS.

182. Amgen representatives were told that the company planned to pursue a parallel course to that which had succeeded with AOC, and request inclusion in a Medical Compendia (such as DrugDex, USPDI and AHFS) and to support physicians who were requesting coverage.

183. The combination of Compendia listing and physician lobbying was calculated by Amgen to provide the same "positive" result as had been achieved by Amgen with respect to AOC.

184. Amgen's MDS marketing scheme gained momentum with the publication of positive MDS studies for the December 2005 American Society of Clinical Oncology ("ASCO"), including a Phase 2 study evaluating the use of 500 mcg of Aranesp Q3W to treat anemia in patients with MDS, followed by a campaign focused on gaining a "Compendia Listing," followed by the physician letter writing campaign. A build up of demand for the product by promotion to the physician population would hopefully gain the same success in the form of new coverage guidelines implemented by the Carrier Medical Directors that would allow regular usage of Procrit or Aranesp for treatment of the anemia associated with MDS.

185. Plaintiff Arriazola received a directive from her district manager to prompt physicians to write letters to Medicare carriers requesting coverage of Aranesp for MDS.

Plaintiff Arriazola's District Manager instructed sales representatives to submit the letters they obtained.

186. Pursuant to her District Manager's instruction, Plaintiff Arriazola obtained a letter of support from Dr. Joel Granick of Midwestern Regional Medical Center ("MRMC") in Zion, IL that was sent to the Medicare Director of WPS. By 2005, WPS changed its coverage guidelines to cover MDS.

187. Notably, MRMC was a large account of Plaintiff Arriazola that prescribed Aranesp off-label for monthly dosing in Oncology patients. Plaintiff Arriazola has personal knowledge of Amgen's monthly dosing scheme.

188. Plaintiff Arriazola also had knowledge of Amgen's off-label promotion of Q2W Aranesp dosing. According to Plaintiff Arriazola, Q2W marketing was fundamental to Amgen's Aranesp marketing efforts and as such, Amgen provided sales representatives and Hospital Systems Managers with a wealth of off-label Q2W marketing materials, including off-label reprints of studies, to keep in their "proof source" binders for use during sales calls.

189. Amgen's off-label dosing marketing schemes for Aranesp were fixed dose marketing schemes, contrary to the FDA-approved Aranesp label, which provided that the dosage was to be adjusted by weight.

2. Neulasta

190. Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

191. The FDA approved dosing is 6 mg administered as a subcutaneous injection to be given 24 hours after chemotherapy.

192. Neulasta was tested as an equivalent to Amgen's already approved Neupogen, which has been marketed since 1991, but required daily injections, and was similarly indicated.

193. Also, Neupogen therapy has been evaluated by the American Society of Clinical Oncology (ASCO), which has developed "evidence based guidelines" for the usage of the broad class of Hematopoetic Growth Factors (also known as Growth Factors or GF). These guidelines have been established, reviewed and revised over the past 10 years based upon the vast quantity of available published literature on this class of drugs. These peer reviewed guidelines recommend using GF's in the first cycle of chemotherapy only when the risk of febrile neutropenia is $\geq$ 40%. The phase 3 clinical trial supporting the approval of Neulasta was conducted in a chemotherapy regimen with a published incidence of 38% febrile neutropenia. The Package Insert for Neulasta (under "Clinical Studies" heading) states "in the absence of growth factor support, similar chemotherapy regimens have been reported to result in a 100% incidence of severe neutropenia (absolute neutrophil count [ANC] $< 0.5 \times 10^9$/L) with a mean duration of 5-7 days, and a 30% to 40% incidence of febrile neutropenia."

194. Amgen began a promotional campaign to encourage physicians to prescribe first cycle use of Neulasta in chemotherapy regimens with an incidence (or risk) of Febrile Neutropenia (FN) of 20% or greater. To support this activity, Amgen provided sales representatives with a single abstract (not a peer-reviewed published trial) that purports to show a significant reduction in FN in breast cancer patients receiving an unconventional

chemotherapy regimen. Based upon that trial, the representatives are directed to imply that all regimens of chemotherapy with an incidence of FN of 20% or greater should receive Neulasta in the first cycle. Because Medicare has no restrictions on reimbursement for Neulasta, physicians can prescribe Neulasta in this fashion contrary to the published ASCO Guidelines. Further, physicians are provided a financial incentive to increase prescriptions of Neulasta by Amgen's contracting and "spread marketing" schemes.

195. A single Neulasta injection costs $2502 (Wholesaler Acquisition Price) with contractual discounts from 20% (hospital) to 26% (clinic) and a Medicare reimbursement rate set at $2507 (Hospital) and $2596 (Physician office). Therefore, typical physician profit or "spread" on a single Neulasta injection is approximately $500. This profit is obtained through a simple subcutaneous injection that takes a nurse approximately 5 minutes to administer.

196. A 20% threshold of FN as compared to a 40% threshold could over time more than double the utilization of Neulasta, and double the costs of treatment funded by the Government-Plaintiffs. Amgen's sales goals increased by 40% in the second half of 2004 in anticipation of this large increase in utilization.

197. Amgen's off-label promotions are also integral parts of the aforementioned scheme to promote products based upon profit or "spread." Off-label usage of Aranesp and Neulasta by medical professionals increase their purchases of Amgen products, and thereby increase both the discount and profits of these same customers.

198. All of Amgen's "off-label" promotional activities constituted false and fraudulent statements as a matter of law under the Food, Drug, and Cosmetics Act, 21

U.S.C. section 331(a) and (b), 352(a) and (f) and regulations promulgated by the FDA to implement that Act.

199. Amgen knew and intended that its "off-label" promotional campaign would improperly increase the submission of claims for reimbursement for off-label prescriptions of Aranesp and Neulasta to government-funded healthcare programs such as Medicare and Medicaid.

200. Absent Amgen's unapproved, illegal off-label marketing and its false statements concerning those medications, physicians would not have believed that it was medically prudent or necessary to write so many prescriptions for Aranesp and Neulasta.

201. Amgen's off-label marketing programs have been extremely successful leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

C. OFF-LABEL PRESCRIPTIONS OF AMGEN'S DRUGS WERE NOT ELIGIBLE FOR REIMBURSEMENT.

202. Medicaid is administered on a state-by-state basis; however, the state programs adhere to federal guidelines. Despite state administration of the program, federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs.

203. The Medicaid program includes individualized provisions, by statute and regulation, concerning reimbursement for prescription drugs, drug utilization review, the eligibility of various drugs for federal financial participation ("FPP"), price controls on prescription drugs and drug manufacturer rebate agreements.

204. According to the Social Security Act, the Plaintiff states are entitled to FFP

for reimbursement for *covered a patient drugs*. 42 U.S.C.A. §1396r-8. The definition of covered outpatient drug is limited to drugs used for medically excepted indications. 42 U.S.C.A. 1396(k)(3). A medically accepted indication is any use approved by the FDA or supported by any of the three specific compendia. *Id.* (k)(6). The compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information and the Drugdex Information System. *Id.* at (g)(1)(b)(i).

205. By way of example, under the Florida Medicaid Program the determination of whether a drug is eligible for reimbursement and prescribed for a purpose that is covered by Medicaid is governed by 42 U.S.C. 1396r-8, Chapter 465 F.S., and the Florida Medicaid Prescribed Drug Services Provider Handbook.

206. In addition to the statutory authority granted by 42 U.S.C. 1396r-8 allowing state Medicaid programs to exclude or otherwise restrict coverage of outpatient prescription drugs, pursuant to the Florida Medicaid Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook to be reimbursed by Medicaid, a drug must be medically necessary and prescribed for medically accepted indications and dosages found in the **(A)** drug labeling ("labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article), the **(B)** American Hospital Formulary Service Drug Information, the **(C)** United States Pharmacopeia-Drug Information or the **(D)** DRUGDEX Information System.

207. Whether the use of a drug meets federal regulation's criteria for coverage is material Medicaid's decision to reimburse for prescription. Consequently, Medicaid (and other government-funded healthcare programs such as Medicare as alleged herein) would deny reimbursement for claims made for prescriptions of Amgen's drugs if it had been

known the purpose for which the drug had been prescribed failed to meet coverage criteria.

208. Use of Amgen's Epogen, Aranesp, Neupogen, Enbrel, Kineret, Kepiance and Neulasta, for example, for the medical conditions and in the dosages alleged herein are not supported by the compendia as medically safe and effective, and therefore should not have been covered by the Medicaid programs. Even to the extent an off-label use of an Amgen drug at issue in this Third Amended Complaint is listed in any of the above-referenced compendia, the listing and studies cited therein do not legally justify coverage of any such off-label use. In other words, the listings fail to legally support any such off-label use. Nonetheless, Amgen recklessly has promoted its drugs for unauthorized, untested and unproven uses through the unlawful methods alleged in this Third Amended Complaint.

209. In addition to Medicaid, the federal government covers in whole or in part the cost of prescription drugs under several other health care programs, including but not limited to Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, the Federal Employees Compensation Act Program, 5 U.S.C. § 8101 *et seq.*, the Bureau of Prisons, State Legal Immigrant Assistance Grants and the Indian Health Service, the Department of Defense, the Department of Labor, and the Public Health Service Entities.

210. Legal restrictions on the coverage of off-label drug use by these programs mirrors the restrictions on coverage under the Medicaid program. See, eg., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

211. For example, Medicare generally does not cover off-label uses of drugs

except when certain criteria is met when off-label uses are supported by the 3 medical compendia cited supra.

212. Similarly, the VA and CHAMPUS/Tri-care programs operate in substantially similar ways to the Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

213. Amgen expected and intended its unlawful promotional efforts to cause claims for reimbursement for off-label uses of its drugs to be submitted to Medicaid, Medicare, Medicare Part D and other government-funded healthcare programs throughout the country. The intended and foreseeable effect Amgen's avaricious scheme was that the these programs would fund the cost of treatment with Amgen's drugs through its reimbursement claims system and accordingly, that Amgen's promotional efforts would directly and substantially increase its drug revenue stream at the expense of, inter alia, Medicare and Medicaid.

214. The Government Plaintiffs were unaware of the unlawful manner in which Amgen promoted its drugs throughout the United States. Amgen knew or should have known about federal regulations governing prescription drug reimbursement under government-funded healthcare programs.

215. Under the Federal False Claims Act, it is unlawful for any "person," as defined by those statutes, to submit a false or fraudulent claim to the United States government, and/or to cause false claims to be submitted. As alleged supra, soliciting, receiving, offering or paying any kickback, bribe or rebate in connection with a claim submitted to the United States Government also renders a claim false as that term is defined by the Federal False Claims Act.

216. The Federal False Claims Act provides for penalties of up to $11,000.00 for each violation of the Act.

217. In summary, throughout the country, Amgen aggressively and intentionally marketed its drugs for non-indicated uses and non-medically necessary uses as described herein. By and through this and other conduct, Amgen caused tens of thousands of prescription reimbursement claims for Amgen drugs prescribed for medically unnecessary and non-indicated uses to be submitted to and paid by the Medicaid/Medicare programs for reimbursement. However, the prescription drug reimbursement claims for off-label uses of Amgen's drugs that Amgen caused to be submitted to the Government Plaintiffs as a direct result of its unlawfully off-label promotion campaign were not eligible for reimbursement from Medicare, Medicaid, the VA or CHAMPUS/Tricare, Medicare Part D and other government-funded healthcare plans described *infra* for the reasons set forth *supra*.

218. Amgen engaged in its national off-label marketing campaign with the knowledge that the majority of prescriptions written as a result thereof would be reimbursed by government-funded health programs such as Medicare and Medicaid, as well as with the knowledge that such prescriptions were for non-medically accepted indications and non-medically necessary uses that the fall outside the coverage of such programs.

IX. AMGEN'S UNLAWFUL REPORTING OF BEST PRICE

219. The complained of unlawful acts and practices involving Amgen's Best Price violations arise from Amgen's provision of substantial rebates and other financial incentives to customers with the knowledge and/or expectation that medical providers and other purchasers would increase and maintain their volume of purchases of Amgen products, the effect of which caused Medicare, Medicaid and other government-funded

healthcare programs to pay more for Amgen drugs than purchasers of Amgen drugs in the private sector.

220. Amgen was required under the Medicaid Rebate Act, 42 U.S.C. § 1396r-8, to report theses discounts as "best prices" for calculating Amgen's rebates to the Plaintiff States. Amgen concealed these rebate discounts from the Centers for Medicare and Medicaid Services ("CMS") which relies on truthful reporting of best price information so that rebates due to the States may be properly calculated. Amgen knowingly, deliberately and purposefully concealed the discounted prices because if it had reported the true discounted prices, Amgen would have had to pay far greater rebates to the States. In addition, by overreporting the best price, Amgen was able to artificially inflate the amount of Medicaid reimbursement for its drugs provided to Amgen customers. This "spread" between government reimbursement and the discounted price paid by Amgen's private customers to acquire its drugs directly or through Amgen wholesalers – which was created as a result of Amgen's intentionally false price reporting – became the cornerstone of Amgen's marketing campaign as is alleged in this complaint *supra*.

221. Amgen's conduct damaged the Medicaid program by way of sophisticated and complicated contractual arrangements that set forth rebate terms with private sector purchasers -- many of which are multi-tiered agreements depending on purchasing volume -- that have the net effect of causing Medicaid programs all across the country to pay more for Amgen drugs that purchasers in the private sector. The contractual arrangements include the Momentum I and II programs and the TOP Program.

A. THE MEDICAID REBATE PROGRAM

222. In 1990, Congress enacted the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, as part of the Omnibus Budget Reconciliation Act of 1990. The Medicaid Rebate Program, also known as the Medicaid Rebate Act and the Medicaid Rebate Statute, is "a cost-savings measure" that Congress passed "(i)n response to increasing Medicaid expenditures for prescription drugs (and) requires drug companies to pay rebates to states on their Medicaid purchases." *Pharmaceutical Research & Mfrs. Of America v. Walsh,* 538 U.S. 644, 649 (2003).

223. Pursuant to the Medicaid Rebate Act, participating manufacturers who want their drugs covered by Medicaid must contract with the federal government in a manner that is consistent with Congressional intent in passing the Medicaid Rebate Act.

224. Drug manufacturers must enter into a Rebate Agreement with the Secretary of HHS in order for federal matching funds to be made available for that manufacturer's covered outpatient drugs, 42 U.S.C. § 1396r-8(a) (1). Each participating manufacturer must sign, indicating agreement and compliance with all provisions therein, including that "The Rebate Agreement shall be construed in accordance with federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme."

225. The Rebate Agreement provides that the Secretary enters the agreement "on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent they have in force an Individual State Agreement)." Upon entering a Rebate Agreement with the Secretary, the manufacturer must pay a quarterly rebate directly to each participating State based on all of the manufacturer's drugs purchased by that State pursuant to its Medicaid plan during that quarter.

226. For single source or innovator multiple source drugs, the basic rebate due on each unit paid for under the State plan is calculated as the greater of either (a) a flat 15.1% off of the average manufacturers' price (AMP) or (b) the difference between the AMP and the "best price," or the lowest price available from the manufacturer during the previous quarter rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or non-excluded government entity. 42 U.S.C. § 1396r-8(c) (1), (2).

227. "The term 'average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." 42 U.S.C. § 1396r-8(k) (1).

228. The best price, or lowest price charged must take into account cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates, other than the rebate paid to the States under the Medicaid Rebate Program. The best price also is determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package. And, the best price does not take into account prices that are merely nominal in amount. 42 U.S.C. § 1396r-8(c) (1).

229. Nominally-priced discounts are intended for not-for-profit, charitable entities and for researchers using the drugs for experimental or non-standard purposes. *See* S. Rep. 102-28 (I), Developments in Aging: 1990-Volume 1, 102nd Cong., 1st Sess. 1991 (March 22, 1991), 1991 WL 52579 (Leg. Hist.). Such discounts are not intended for marketing purposes. The Rebate Agreement defines "nominal price" as "any price less than 10% of

the AMP in the same quarter for which the AMP is computed." Rebate Agreement at I. Definitions, (s).

230. Any rebate amounts received by the State must be offset against the State's Medicaid expenditures that quarter for purposes of calculating the matching federal financial participation. 42 U.S.C. § 1396r-8(b) (1) (B).

231. Drug manufacturers are required under the Medicaid Rebate Statute and Rebate Agreement to calculate and report their AMPs and best prices to the Secretary on a quarterly basis. 42 U.S.C. § 1396r-8(b) (3) (A) (i); Rebate Agreement at § II (e). Any information provided by a manufacturer or wholesaler under the rebate statute is confidential and "shall not be disclosed by the Secretary…or a State agency…except as the Secretary determines to be necessary to carry out this section." 42 U.S.C. § 1396r-8(b) (3) (D); Rebate Agreement at § VII.

232. States are required to report their total Medicaid drug utilization to each manufacturer and the Secretary sixty days after the end of the rebate quarter. 42 U.S.C. § 1396r-8(b) (2) (A). Using the manufacturer pricing data, CMS computes the unit rebate amount ("URA") "to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due." Rebate Agreement at § I (dd). Using the Medicaid drug utilization data, manufacturers calculate and pay the States the rebates they believe are due and owing to each State.

233. The Government Plaintiffs relied, and continue to rely, upon the benefits conferred by the Medicaid Rebate program, and on the performance of Amgen of the obligations imposed by Rebate Agreements, to ensure that the Medicaid Program

reimburses payors, e.g., pharmacies, based on the actual Best Price available for Amgen's drugs.

B. AMGEN'S FALSE AND FRAUDULENT REPORTING OF BEST PRICE.

234. As alleged in this Third Amended Complaint, at all times relevant hereto, Amgen has been entrenched in a battle for market share for its drugs including Epogen, Aranesp, Neupogen, Enbrel, Kineret, Neulasta and Sensipar. To beat the competition, Amgen employs illegal marketing strategies and promotional schemes to induce hospitals, clinics and doctors to prescribe Amgen's drugs over other competitors. These marketing strategies were rolled out to the public in the form of programs providing for off-invoice price discounts, as has been alleged in detailed herein.

235. Amgen's illegal contracts included the Enhanced Momentum II, TOP and APC described *supra* and the misuse of Physician Practice Management Groups ("PPMs").

236. During her employment with Amgen from 1999 through 2005, Plaintiff learned first hand that Amgen had devised, drafted and entered into improper contracts with private and public hospitals and/or clinics. The improper contracts included various improper inducements, including rebates and discounts, designed to increase Amgen's market share of specific products and to increase its overall volume of sales at the expense of the taxpayers. These inducements were devised by Amgen to encourage its customers to increase prescriptions of Amgen's drugs over competing drugs or alternative forms of medical care and treatment, not to ensure that the most medically appropriate treatment was provided.

237. The complained of unlawful schemes are evidenced in contractual agreements entered into between Amgen and the following hospitals and clinics, of which Plaintiff Arriazola has first hand knowledge:

HOSPITAL
Evanston Hospital
George Carro, RPh, MS
Evanston, IL

Glenbrook Hospital
Amanda Niemi, PharmD
Glenview, IL
Highland Park Hospital
Gary Gehrke, PharmD
Highland Park, IL
Holy Family Medical Center
Mala Singh, PharmD, MS
Des Plaines, IL
Lake Forest Hospital
Gregg Helm, PharmD
Lake Forest, IL

Lutheran General Hospital
Bonnie Bachenheimer, PharmD
Park Ridge, IL
North Suburban Medical Consultants
Leonard A. Kosova, MD
Niles, IL

Condell Medical Center
Kati Kwasiborski, RPh
Libertyville, IL
Rush North Shore Medical center
Carol Heunisch, PharmD
Skokie, IL

St. Francis Hospital
Susan Pahl, RPh
Evanston, IL
Resurrection Medical Center
Joseph R. Gera, RPh
Chicago, IL
Swedish Covenant Hospital
Chicago, IL
Cancer Center- K. Joseph Philip, MD- Chief of Oncology Department
Inpatient Hospital Pharmacy- Ramesh V. Patel, PharmD
Rush University Medical Center
The Rush Cancer Institute
Matthew A. Kemper, PharmD
Chicago, IL
John H. Stroger, Jr Hospital of Cook County
Pamela L. Sperl, PharmD
Chicago, IL
MacNeal Health Network
William Pong, PharmD
Berwyn, IL
Louis A. Weiss Memorial Hospital
Chicago, IL
Jesse Brown VA Medical Center
Richard J. Rooney, PharmD
Chicago, IL

CLINIC
Glen Morton Medical Center
Chicago and Morton Grove, Illinois

Hematology Oncology Associates of Illinois
Leon H. Dragon, MD
Highland Park, IL
Hematology Oncology Associates of Illinois
Ira A. Oliff, MD
Skokie, IL
Block Medical Center
Keith I. Block, MD
Evanston, IL
Deerpath Medical Oncology/Hematology
Rohit R. Shah, MD
Ira J. Piel, MD
Lake Forest, IL
Oncology Specialists, SC
Rossini Parayno, PharmD
Park Ridge, IL
North Shore Oncology Hematology Associates, Ltd
Peter Muhlbach- Business Manager
Barrington, IL
Libertyville, IL
Midwestern Regional Medical Center
Cancer Treatment Centers of America
Robert E. Musick, RPH
Oncology Hematology Associates of Northern Illinois, Ltd
Naren Kapadia, MD
Nilesh D. Mehta, MD
Gurnee, IL
Progressive Care, SC
Mark E. Singer- Chief Operating Officer
Chicago, IL

University of Chicago
Abdul S. Manasrah, MS- Finance Manager
Chicago, IL
University of Illinois
Divyesh Mehta, MD- Chief Oncology
John Gargas- Pharmacy
Andrew Donneley, Pharm D- Pharmacy
Chicago, IL
University of Wisconsin-Madison Hospital
Madison, Wisconsin

1. THE ENHANCED MOMENTUM II HOSPITAL CONTRACT.

238. As set forth *supra*, under the terms of Amgen's Momentum II contracts, hospitals clients receive off-invoice discounts of 25% on their purchases of Aranesp vials and singlejects and 2% off the purchases of Neulasta and Neupogen. Hospital-based dialysis centers receive off-invoice discounts of 11% on all Epogen vials, with the exception of Epogen M20 vials for which an off-invoice discount of 17% is provided. Hospitals without dialysis centers receive discounts of 3% on all Epogen vials.

239. Further, effective October 1, 2004, pursuant to Amgen's Momentum II contract, hospitals also receive unreported rebates from Amgen based on the market share of Aranesp and volume of sales of Neulasta and Neupogen. Addition of rebates on Neupogen and Neulasta based upon Aranesp market share constitutes an illegal bundling of products that was intended to increase the incentive to purchase Aranesp without further reducing the price of Aranesp. In other words, Amgen used the discounts on Neupogen and Neulasta to provide additional rebates tied to Aranesp purchases which Amgen would not calculate as Aranesp discounts.

240. Amgen regularly monitored and reported customers "red to white" ratio as a way for representatives and management to measure the economic power of the bundled discounts. The larger a customer's purchase of "white" blood growth factors such as Neupogen and Neulasta was relative to the "red" blood growth factors Aranesp and Procrit,

the more significant the customer's additional bundled discounts would be, and the greater the bundled incentive would become as compared to unbundled discount offerings by competitor Johnson and Johnson, sellers of Procrit.

241. The hospitals received rebates of up to 21.5% on its total quarterly purchases of Aranesp based on this drug's market share at the hospital. The hospitals also receive rebates of up to 8% on its quarterly purchases of Neupogen and Neulasta, with the rebate amounts directly tied to Aranesp's market share.

242. To receive the rebate on the purchases of Neulasta and Neupogen, the hospital's net quarterly purchases have to be equal to or greater than 70% of the prior year's same-quarter net purchases.

243. By offering these increased off invoice discounts and rebates based on the market share of Aranesp and continued high purchase volumes of Neulasta and Neupogen, Amgen improperly induced the hospitals to prescribe and sell Amgen's drugs over competing drugs or alternative forms of medical care and treatment. The scheme interfered with the healthcare provider's ability to make unbiased and neutral judgments as to the appropriate medicines to use, including off-label use.

244. Amgen knew that the rebates provided to private purchasers through its Momentum II hospital contracts must be reported to CMS pursuant to the Medicaid Rebate Act and Amgen's Rebate Agreement with CMS. Even so, Amgen purposefully failed to report the cumulative result of the rebates associated with the Momentum II contracts as required under the Medicaid Rebate Act. Amgen knowingly and deliberately concealed these discounts for the purposes of Best Price and AMP and knowingly did not account for the steep discounts offered under the Momentum II hospital contracts in calculating its

quarterly report of AMP or best price to CMS. Had Amgen truthfully reported these prices, it would have affected the best price calculations and Amgen would have been legally obligated to pay the Medicaid program and other government-funded health care programs much greater rebates. In addition, had Amgen truthfully reported Amgen drug prices, Amgen would have effectively eliminated the "spread" it relied upon so heavily to induce purchases of its drugs over competitors.

245. Amgen knowingly did not disclose these discounts and knowingly did not account for the steep discounts offered under the Momentum II hospital contracts in calculating its quarterly report of AMP or best price to CMS.

2. THE TOTAL ONCOLOGY PARTNER PROGRAM

246. The TOP program similarly also offered illegal inducements to participant hospitals in the form of rebates in two discrete ways.

247. As alleged *supra*, the TOP program provides for rebates to private hospitals based on the increase in product market share of Amgen's products at individual hospitals. Specifically, when Amgen's product market share increases by 1.5% to 9.49% in a given quarter, the hospital is given a rebate of 21.5% on its Aranesp purchases and a rebate of 2% to 4% on its purchases of Neulasta and Neupogen.

248. If Amgen's quarterly product market share at the hospital is at least 79.5% or the market share increases by 9.5% or more in the quarter, the hospital receives a rebate of 21.5% on Aranesp and a rebate of 7% on the purchases of Neulasta and Neupogen.

249. Further, if the hospital was a partner in both the Momentum II and TOP programs, it is entitled to combine its rebate percentages for its eligible Neulasta and Neupogen purchases. By tying together these two programs and offering increased rebates

based on the level of Amgen's market share, this scheme interfered with the hospitals' ability to make unbiased and neutral professional judgments as to the appropriate medicines to use and purchase for the care of its patients.

250. Amgen knew that the rebates provided to private purchasers through its TOP contracts must be reported to CMS pursuant to the Medicaid Rebate Act and Amgen's Rebate Agreement with CMS. Even so, Amgen purposefully failed to report the cumulative result of the rebates associated with the TOP program as required under the Medicaid Rebate Act. Amgen knowingly and deliberately concealed these discounts for the and knowingly did not account for the steep discounts offered under the TOP program in calculating its quarterly report of AMP and best price to CMS. Had Amgen truthfully reported these prices, they would have affected the best price calculations and Amgen would have paid much greater rebates to the Medicaid program. In addition, had Amgen truthfully reported Amgen drug prices, Amgen would have effectively eliminated the "spread" it relied upon so heavily to induce purchases of its drugs over competitors.

3. THE APC CONTRACT.

251. As set forth *supra*, under the terms of Amgen's APC contract, physician clinics receive off-invoice discounts and unreported rebates from Amgen based on the market share of Aranesp and volume of sales of Neulasta and Neupogen. Addition of rebates on Neupogen and Neulasta based upon Aranesp market share constitutes an illegal bundling of products that was intended to increase the incentive to purchase Aranesp without further reducing the price of Aranesp. In other words, Amgen used the discounts on Neupogen and Neulasta to provide additional rebates tied to Aranesp purchases which Amgen would not calculate as Aranesp discounts.

252. By offering these increased off invoice discounts and rebates based on the market share of Aranesp and continued high purchase volumes of Neulasta and Neupogen, Amgen improperly induced physician clinics to prescribe and sell Amgen's drugs over competing drugs or alternative forms of medical care and treatment. The scheme interfered with healthcare providers' ability to make unbiased and neutral judgments as to the appropriate medicines to use, including off-label use.

253. Amgen knew that the rebates provided to private purchasers through its APC contracts must be reported to CMS pursuant to the Medicaid Rebate Act and Amgen's Rebate Agreement with CMS. Even so, Amgen purposefully failed to report the cumulative result of the rebates associated with the APC contracts as required under the Medicaid Rebate Act. Amgen knowingly and deliberately concealed these discounts for the purposes of Best Price and AMP and knowingly did not account for the steep discounts offered under the APC contracts in calculating its quarterly report of AMP or best price to CMS. Had Amgen truthfully reported these prices, it would have affected the best price calculations and Amgen would have been legally obligated to pay the Medicaid program and other government-funded health care programs much greater rebates. In addition, had Amgen truthfully reported Amgen drug prices, Amgen would have effectively eliminated the "spread" it relied upon so heavily to induce purchases of its drugs over competitors.

254. Amgen knowingly did not disclose these discounts and knowingly did not account for the steep discounts offered under the APC physician clinic contracts in calculating its quarterly report of AMP or best price to CMS.

D. AMGEN'S IMPROPER USE OF UNRESTRICTED EDUCATIONAL GRANTS AND PATIENT EDUCATION GRANTS TO INFLUENCE HOSPITALS AND OTHERS, AS WELL AS TO DISGUISE PRICE REBATES THAT AMGEN INTENTIONALLY FAILED TO REPORT.

255. In an effort to increase its volume of sales with existing customers, namely, hospitals, Amgen would make what were known as unrestricted educational grants to various physicians, hospitals, and other institutions. These grants would often be in the form of a sponsorship of a seminar or meeting held at existing or potential customer facilities. The sponsored speaker(s) would discuss disease processes and stages and further discuss how Amgen products were clinically and economically beneficial in the treatment of these diseases.

256. Although Amgen would state in letters and other materials related to grants of this nature that there was no expectation of any quid pro quo, there was an implicit understanding that the grantee would increase its purchases of Amgen's drugs and/or its speakers would advocate the use of Amgen's drugs to other attendees at the seminar.

257. By way of example, in January, 2005, Amgen was asked to make such a grant to Rush University Medical Center for its 5th Annual Rush Review. Various seminars were planned to discuss synopses of the latest clinically relevant research. Amgen provided a grant in the amount of $10,000 in support of this seminar and there was an unspoken expectation that the hospital would increase its purchases of Amgen products and/or speakers at the seminar would comment favorably on the Defendant's products, including Aranesp.

258. These grants were illegal inducements to the hospitals to change or switch their prescribing and billing habits in order to create financial incentives for greater Amgen product use.

259. In addition to the unregistered education grants, Amgen would also supply what were known as Patient Education Grants ("PEGs").

260. These grants were made to various hospitals for the purchase of various education materials and other supplies a hospital needed to create a patient education center. These materials would consist, in part, of books, and research materials on cancer and the various treatments.

261. In exchange for providing funds for these centers or rooms, the hospitals were expected to increase or maintain their purchase of Amgen pharmaceutical products. This was an implicit understanding as Amgen was careful not to state its expectations in any correspondence related to these grants.

262. For example, in 2005, the University of Illinois Medical Center received a PEG in the amount of $5,000.00 from Amgen to establish such a center.

263. These grants were illegal inducements to the hospitals to change or switch their prescribing and billing habits in order to create financial incentives for greater Amgen product use.

E. AMGEN'S KNOWINGLY UTILIZED PHYSICIAN PRACTICE MANAGEMENT ORGANIZATIONS TO EVADE BEST PRICE REPORTING REQUIREMENTS.

264. Pursuant to a scheme separate from that implemented through the hospital and clinic contracts, but in a similar fashion, Amgen entered into purchase contracts with for-profit physician-owned clinics to provide discounts and rebates tied to the purchase of Aranesp, Neupogen and Neulasta. Plaintiff Arriazola, as an Amgen Professional Sales Representative (or PSR), was responsible for presenting these contracts to physician clinics,

gaining signatures from the appropriate clinic personnel, and monitoring and communicating the status of discounts and rebates to the contracted customers.

265. The physician clinics would purchase Amgen products at a discounted price, administer the product to patients, and then submit Amgen drug reimbursement claims to the patient, and/or the insurer, Medicare and Medicaid for the administered Amgen drug and an administration fee, and sometimes for a clinic visit as well.

266. Physician clinic agreements were offered either directly to a clinic, or through a Physician Practice Management organization (PPM), which Amgen also referred to internally as a "Buying Group." The PPM contracts were the same as those offered directly to clinics; however, the PPM contracts offered additional features such as add on discounts that Amgen funded through various payments from Amgen to the PPM groups. These groups included International Oncology Network (ION), National Oncology Alliance (NOA) and other small or regional PPM groups. Amgen funded these added discounts *via* cash discounts, administration fees, data collection fees and chargebacks.

267. Working through the PPM contracts, Amgen could offer physician practices discounts that amounted to as much as 6-8% *in addition to* the prevailing Amgen APC contract.

268. Amgen worked with a PPM partner and an approved wholesaler. Each PPM generally utilized a selected or contracted wholesaler. Plaintiff Arriazola questioned the need and rationale for contracting through PPMs, including involvement of wholesalers.

269. The PPM/wholesaler distribution scheme worked as follows:

a. Amgen sold products to the wholesaler at the Wholesaler Acquisition Price, or WAP, which was the list price for the drug. Terms for the purchase were 2% 30, net 60, referred to as the "cash discount."

b. The wholesaler sold the drug to the PPM member physician clinic at the off-invoice discount price (APC customers received 10% off invoice discount for Aranesp and 5% off invoice for Neupogen and Neulasta.) The wholesaler then reported the customer purchase back to Amgen.

c. The wholesaler received a cash discount of 2% 30, net 60 days from Amgen, and a 2-3% "chargeback" for reporting the sale of the product to the contracted customer to Amgen. Amgen also credited the wholesaler with the off-invoice discount that was passed on to the customer. In this way, the wholesaler was made whole for the "off-invoice" discount, and reaped 4-5% discounts in the form of cash discounts and "chargeback" fees.

d. The wholesalers used their combined cash discount and chargeback fees to offer additional cash discounts to clinic customers. Clinic customers who paid with a bank transfer or within 10 days could reap 3.75% cash discounts.

e. The PPM group would also receive an administration fee of 2% of the total purchases of contracted Amgen products. Amgen would then offer discounts of up to an additional 4% for purchases made by the PPM contracted customers. These rebates were paid directly by the PPM, and thus did not come directly from Amgen, although the money to pay the rebates came from Amgen through contractual agreement with the PPM.

f. Amgen preferred to use this distributor marketing channel because it could incentivize its clinic customers with several percentage points of additional discount

that was passed through other channel partners. Because these additional rebates and discounts were not paid directly by Amgen, but through a third party, these discounts were not reported by Amgen to CMS for the purposes of calculating best price. The discounts were closely monitored and dictated by Amgen, and used in Amgen promotion of their products. Amgen made it known to customers that these were additional discounts credited to purchase of Amgen products through the wholesalers and PPM groups.

g. In this fashion, Amgen provided discounts of up to 7.75% on their product purchases that were not used to calculate Medicaid Best Price.

h. When the discounts were provided to the customer, Amgen told the customer that they were responsible for reporting all discounts in accordance with applicable state and federal laws. However, this method was not used to calculate Best Price.

270. As set forth above, Amgen knowingly utilized PBMs to cover up its multi-tiered rebate schemes and to avoid reporting the same to CMS in violation of the Medicaid Rebate Act's Best Price requirements.

X. FEDERAL HEALTHCARE PROGRAMS DAMAGED BY AMGEN'S FRAUDULENT AND ILLEGAL PRACTICES

A. MEDICAID AND MEDICARE

1. The Medicaid Program

271. Title XIX of the Social Security Act is a program that provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children. Among the health benefits funded primarily

by Medicaid, up until January 1, 2006, was funding for the prescription drug needs of the Program's beneficiaries.

272. At all times relevant to this action, in most states, Medicaid was an open-ended federal-state matching program. The federal government contributes a fixed percentage of each state's Medicaid costs each year; however, the exact percentage the federal government contributes varies year to year using a formula that takes into account each state's per capita income relative to the national per capita income. The percentage of state contribution the funding of prescription drug purchases, and all other covered Medicaid health benefits, typically has amounted to at least 40% at all times relevant to the Complaint.

273. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs as described *supra*.

2. The Medicare, Medicare Part B and Medicare Part D Programs

274. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. The health insurance provided to beneficiaries of the Medicare insurance program is paid in whole or in part by the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals sixty-five (65) and over. Payments made under the Medicare Program include payment for certain prescription drugs used during treatment at an appropriate medical faculty and otherwise, as well as certain injectable drugs and drugs used in conjunction with the treatment of patients with cancer and chronic kidney disease.

275. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare ("Medicare Part D").

276. Medicare Part D went into effect on January 1, 2006. The Program is administered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid ("CMS"). For "dual eligibles," defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for other health care in 2005, enrollment in Medicare Part D was compulsory. Such beneficiaries were automatically switched to Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

277. Coverage of prescription drugs under Medicare Part D is subject to the same regulations as coverage under the Medicaid Program described above.

278. Some of Amgen drugs at issue in this Fourth Amended Complaint, including Aranesp and Neupogen, are covered by Medicare Part B in addition to Medicare Part D, depending where and how the drugs are administered.

279. The Medicare Modernization Act (MMA), Section 1847A of the Social Security Act (SSA), changed reimbursement for Medicare Part B drugs from 95% of average wholesale price (AWP) to 106% of ASP net of volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than Medicaid rebates).

280. Medicare reimbursement is based on the lesser of this allowable amount or actual charges, as follows:

- Physician offices are reimbursed for 80% of the allowable amount

- The patient or patient's secondary insurer is responsible for the remaining 20% coinsurance

281. Since January 2005, Medicare Part B has been paying for most covered drugs using a reimbursement methodology based on ASPs. Section 1847A(c) of the Social Security Act, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, defines an ASP as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.

282. A manufacturer's ASP must be calculated by the manufacturer every calendar quarter and submitted to CMS within thirty (30) days of the close of the quarter. Each report must be certified by one of the following: the manufacturer's Chief Executive Officer (CEO); the manufacturer's Chief Financial Officer (CFO); an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

283. Manufacturers report ASPs by national drug codes (NDC), which are 11-digit identifiers that indicate the manufacturer, product dosage form, and package size of the drug. Manufacturers must provide CMS with the ASP and volume of sales for each NDC on a quarterly basis, with submissions due 30 days after the close of each quarter.

284. Because Medicare Part B reimbursement for outpatient drugs is based on HCPCS codes rather than NDCs and more than one NDC may meet the definition of a particular

HCPCS code, CMS has developed a file that "crosswalks" manufacturers' NDCs to HCPCS codes. CMS uses information in this crosswalk file to calculate volume-weighted ASPs for covered HCPCS codes.

285. Just as it has manipulated the AMP/best price for its drugs under the Medicaid Rebate Act, Amgen has manipulated the ASP for its drugs reimbursed under Medicare Part B for its financial gain.

B. OTHER FEDERALLY FUNDED HEALTH CARE PROGRAMS

286. In addition to Medicaid, Medicare and Medicare Part D, the federal government reimburses a portion of the cost of prescription drugs under several other health care programs, including but not limited to the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), the Indian Health Service and CHAMP VA, as alleged below. These programs operate in similar ways to the Medicare and Medicaid programs. For example, the VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

1. The Railroad Retirement Medicare Program

287. The Railroad Retirement Medicare program is authorized by the railroad retirement act of 1974, at U.S.C.A. §231 *et seq.* It is administered through the United States Railroad Retirement Board, "RRB," and furnishes Medicare coverage to retired railroad employees.

2. Federal Employee Health Benefit Plans

288. The Federal Employees Health Benefits Program ("FEHBP") is administered by the United States Office of Personnel Management ("OPM") pursuant to 5

U.S.C.A §8901 *et seq.* and provides health care coverage to federal employees, retirees and their dependants and survivors.

3. Tri-Care

289. The Tri-Care program, formerly, CHAMPUS, is administered by the United States Department of Defense through its component in agency, CHAMPUS, under the authority of 10 U.S.C.A. §§1701-1106. It is a health care program that provides for care in civilian facilities for members of the uniformed services and their dependents. Pursuant to 38 U.S.C.A. §8126, and the regulations based there on, drugs furnished by drug manufacturers to the Department of Defense must be furnished at the best price.

290. Upon information and belief and base their own relators a ledge that the United States also furnishes funds which several states used to pay for such drugs pursuant to the State Legal Immigrant assistance Grants, 8 U.S.C.A. §1255a; 45 C.F.R. §402.10.

4. The Veterans Administration

291. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") is a comprehensive health care program in which the VA shares the cost of covered health care services and supplies with eligible beneficiaries. The program is administered by Health Administration Center and our offices are located in Denver, Colorado. In general our CHAMPVA program covers most health care services and supplies that are medically and psychologically necessary.

292. Due to the similarity between CHAMPVA and the Department of Defense ("DoD") Tri-Care program the two are often mistaken for each other. CHAMPVA is a Department of Veterans Affairs program whereas Tri-Care is a regionally managed health care program for active duty and retired members of the uniformed services, their families

and survivors. In some cases a veterans may look to be eligible for both/either program on paper. However, military retirees, or the spouse of a veteran who was killed in action, are and will always be Tri-Care beneficiaries.

293. Pursuant to 38 U.S.C.A. §8126, and the regulations based thereon, and contracts the Veterans Administration had with manufacturers, drugs furnished to the Veterans' Administration by drug manufacturers must be furnished at the best price.

294. The VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

5. Indian Health Service

295. The Indian health service is responsible for providing comprehensive health services to more than 1,400,000 Americans. It is administered by the department of health and human services pursuant to 42 U.S.C.A. 2002 *et seq.* The statute authorizes the Secretary to enter into contracts with independent providers to furnish health services to Native Americans whenever the Secretary determines that independent providers can better meet the population's need. Pursuant to 38 U.S.C.A. §8126, and the regulations based thereon, drugs furnished to the Indian Health Service by drug manufacturers must be furnished at the best price.

6. State Legal Immigrant Assistance Grants

296. Relator is informed and believes and based thereon alleges that the United State also furnishes funds which several States use to pay for such drugs pursuant to State Legal Immigrant Assistance Grants, 8 U.S.C.A §1255A; 45 C.F.R. §402.10.

C. THE GOVERNMENT HEALTH PROGRAMS WERE DAMAGED

297. During the time relevant to this Third Amended Complaint, many of the off-label uses of Amgen's drugs promoted by Amgen as alleged herein were not eligible for reimbursement under Medicaid, Medicare and the other government healthcare programs as set forth above.

298. Additionally, because Amgen's unlawful marketing efforts were designed to generate overutilization of their drugs in situations which the drugs either were not proven safe or effective or were not medically necessary for treatment of patients' specific medical conditions, Amgen caused health care providers to submit claims for reimbursement to Medicaid, Medicare and the other government health programs that were unwarranted and not covered and therefore false.

COUNT ONE
Federal False Claims Act
31 U.S.C. §3729(a)(1)
Presenting or Causing to be Presented False Claims[2]

299. Plaintiffs Arriazola and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

300. This is a *qui tam* action brought by Arriazola and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

301. The Federal False Claims Act, 31 U.S.C. §3729(a)(1) provides:

> (a) Liability for certain acts. Any person who--
>
> (1) Knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed

[2] For all unlawful conduct for which Defendants are liable under this count that occurred on or after May 20, 2009, the date on which Congress amended and renumbered the Federal False Claims Act, this Third Amended Complaint should be deemed to include violations of the FCA as amended, eg, 31 U.S.C. (a)(1)(A).

Forces of the United States a false or fraudulent claim for payment or approval

Id.

302. By virtue of the above-described acts, among others, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval, and possibly continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States, in violation of 27 U.S.C. §3729(a)(1). For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta, Sensipar and its other drugs would not have been submitted, and thereafter paid by the United States, but for the illegal practices of Defendants described in this complaint.

303. In addition, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes, or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with the Anti-Kickback Statute is a condition precedent for reimbursement under the Medicaid, Medicare and other federally-funded health programs.

304. By engaging in the fraudulent and illegal practices described herein, Defendants violated the Anti-Kickback Statute. Defendants' material violations of the Anti-Kickback Statute lead to the submission of claims for Amgen drug to the United States. Those claims were false, as they were ineligible for reimbursement, and therefore by submitting or causing these false claims to be submitted, Defendants further violated 31 U.S.C. §3729(a)(1) from at least 1998 to the present.

305. Plaintiff United States, unaware of the falsity of the claims and/or statements which the Defendants caused doctors, pharmacies hospitals and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid said doctors, hospitals, pharmacies and other health care providers for claims that would otherwise not have been allowed. These claims – prescription drug reimbursement claims for Amgen's drugs – were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

306. For those claims that Defendants' caused to be submitted, it was foreseeable and in fact the intended result that those claims would be submitted.

307. By reason of Amgen's unlawful practices, substantial numbers of doctors, hospitals, pharmacies and other health care providers in the United States have been induced to purchase substantial quantities of Amgen's drugs and these practices thus provided substantial profits to Defendants.

308. By reason of these unlawful practices by Amgen, as aforesaid, doctors, hospitals, pharmacies and other health care providers have been induced to purchase Amgen's drugs rather than recommending less expensive procedures or treatment options for their patients.

309. The amounts of the false or fraudulent claims to the United States were material. Plaintiff United States, being unaware of the falsity of the claims and/or statements caused to be made by Defendants, and in reliance on the accuracy thereof paid and may continue to pay for Amgen's unlawfully induced prescriptions.

310. It is believed that as a result of Defendants' violations of 27 U.S.C. 3729§ (a)(1) the United States has been damaged in an amount far in excess of millions of dollars

exclusive of interest. By reason of Defendants violations of 27 U.S.C. 3729 §(a)(1), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim presented or caused to be presented by Defendants.

311. Arriazola is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of herself and the United States.

COUNT TWO
Federal False Claims Act
31 U.S.C. §3729(a)(2)
Creation or Use of False Statements or Records to Obtain Payment[3]

312. Plaintiffs Arriazola and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

313. This is a *qui tam* action brought by Arriazola and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

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[3] On May 20 2009, Congress passed the Fraud Enforcement and Recovery Act ("FERA"), Pub.L. No. 111-21, 123 Stat. 1617 (2009), which amended and renumbered this provision as §3729(a)(1)(B), *see* FERA § 4(a), 123 Stat. at 1621. The amendment to § 3729(a)(2) was made retroactive to June 7, 2008, applicable to "all claims under the False Claims Act ... that [were] pending on or after that date," FERA § 4(f), 123 Stat. at 1625. Because Plaintiff's claim was pending as of June 7, 2008, the potentially applicable provisions in this case is current §3729(a)(1)(B), establishing liability for "knowingly mak[ing], us [ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim," *see* FERA § 4(a), 123 Stat. at 1621 in accord with the Court of Appeals for the Second Circuit's ruling in *United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94 (2d Cir. 2010) (quoting FERA §4(a), 123 Stat. at 1621), reversed and remanded on other grounds, *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 131 S.Ct. 1885 (2011). However, to the extent that the FERA amendment to this section is deemed retroactive only to false claims defined as claims for payment pending on June 7, 2008, Plaintiff asserts that this count should be deemed to include violations of the FCA under §3729(A)(1)(B) for violations of this section that occurred after June 7, 2008.

314. The Federal False Claims Act, 31 U.S.C. §3729(a)(2) provides:

> (a) Liability for certain acts. Any person who--
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; ... is liable to the United States Government for a civil penalty of not less than $ 5,500 and not more than $11,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, ...

Id.

315. By virtue of the above-described acts, among others, Defendants knowingly made used or caused to be made or used false records or statements to get false claims paid by the United States, and possibly continues to do so, in violation of 27 U.S.C. §3729(a)(2).

316. In addition, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with the Anti-Kickback Statute is a condition precedent for reimbursement under the Medicaid, Medicare and other federally-funded health programs.

317. By engaging in the fraudulent and illegal practices described herein, Defendants violated the Anti-Kickback Statute. Defendants' material violations of the Anti-Kickback Statute lead to the submission of claims for Amgen drug to the United States. Those claims were false, as they were ineligible for reimbursement, and therefore by submitting or causing these false claims to be submitted, Defendants further violated 31 U.S.C. §3729(a)(2) from at least 1998 to the present.

318. Plaintiff United States, unaware of the falsity of the records and/or statements which the Defendants caused doctors, pharmacies hospitals and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid said doctors, hospitals, pharmacies and other health care providers for claims that would otherwise not have been allowed. These claims – prescription drug reimbursement claims for Amgen's drugs – were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

319. For those records and/or statements that Defendants' caused to be made or used, it was foreseeable and in fact the intended result that those statements and/or records would result in the payment of false reimbursement claims for Amgen drugs.

320. By reason of Amgen's unlawful practices, substantial numbers of doctors, hospitals, pharmacies and other health care providers in the United States have been induced to purchase substantial quantities of Amgen's drugs and these practices thus provided substantial profits to Defendants.

321. By reason of these unlawful practices by Amgen, as aforesaid, doctors, hospitals, pharmacies and other health care providers have been induced to purchase Amgen's drugs rather than recommending less expensive procedures or treatment options for their patients.

322. The amounts of the false or fraudulent claims caused to be paid pursuant to Defendants false records and statements to the United States were material. Plaintiff United States, being unaware of the falsity of the records and/or statements made or caused to be made by Defendants, and in reliance on the accuracy thereof, paid claims that Defendants knew to be false, as they intended.

323. It is believed that as a result of Defendants' violations of 27 U.S.C. §3729 (a)(2) the United States has been damaged in an amount far in excess of millions of dollars exclusive of interest. By reason of Defendants violations of 27 U.S.C. §3729 (a)(2), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendants. Further, at all times relevant hereto, Defendants made or caused to be made false records and statements with the intent that the Government Plaintiffs pay false claims.

324. Arriazola is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of herself and the United States.

COUNT THREE
Federal False Claims Act
31 U.S.C. §3729(a)(3)[4]
Conspiracy

325. Plaintiffs Arriazola and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

326. This is a *qui tam* action brought by Arriazola and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

327. The Federal False Claims Act, 31 U.S.C. §3729(a)(3) provides:

[4] For all unlawful conduct for which Defendants are liable under this count that occurred on or after May 20, 2009, the date on which Congress amended and renumbered the Federal False Claims Act, this Third Amended Complaint should be deemed to include violations of the FCA as amended, eg, 31 U.S.C. (a)(1)(C).

> (a) Liability for certain acts. Any person who—
>
> (3) Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; …is liable to the United States Government for a civil penalty of not less than $ 5,500 and not more than $11,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, …

Id.

328. In violation of 31 U.S.C. §3729(a)(3), Defendant Amgen entered into conspiracies with Immunex, medical providers, Medicare Medical Directors, hospitals, paid consultants including but not limited to Jim Stephenson, Professional Advisory Boards and Pharmacy Advisory Boards to defraud the Plaintiff United States.

329. By the foregoing acts and omissions, Defendant Amgen took actions in furtherance of its conspiracies, including but not limited to the payment of substantial sums of monies and/or illegal kickbacks to its co-conspirators as well as entering into unlawful contracts.

330. By the foregoing acts and omissions, Defendant Amgen conspired with Immunex, medical providers, Medicare Medical Directors, hospitals, paid consultants including but not limited to Jim Stephenson, Professional Advisory Boards and Pharmacy Advisory Boards to defraud the United States by getting false and fraudulent claims paid and approved in violation of the False Claims Act, 31 U.S.C. §3729(a)(3).

331. As a consequence of Defendants' violations of 27 U.S.C. §3729 (a)(3) the United States has been damaged in an amount far in excess of millions of dollars exclusive of interest. By reason of Defendants' violations of 27 U.S.C. §3729 (a)(3), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim Defendants

conspired to get paid or allowed. Further, at all times relevant hereto, the conspirators intended to defraud the Government.

332. Arriazola is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of herself and the United States.

COUNT FOUR
Federal False Claims Act
31 U.S.C. §3729(a)(7)[5]
Making or Using or Causing to be Made or Used False Record to Avoid or Decrease an Obligation to Pay Monies

333. Plaintiffs Arriazola and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

334. This is a *qui tam* action brought by Arriazola and the United States to recover treble damages, civil penalties and the cost of this action under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

335. The Federal False Claims Act, 31 U.S.C. §3729(a)(7) provides:

> (a) Liability for certain acts. Any person who—
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $ 5,500 and not more than $11,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, …

Id.

336. Amgen is a manufacturer of drugs included in the Medicaid drug formulary. These drugs include Epogen, Aranesp, and Neupogen, Enbrel, Kineret and Neulasta.

[5] For all unlawful conduct for which Defendants are liable under this count that occurred on or after May 20, 2009, the date on which Congress amended and renumbered the Federal False Claims Act, this Third Amended Complaint should be deemed to include violations of the FCA as amended, eg, 31 U.S.C. (a)(1)(G).

337. Accordingly, as a condition precedent to Amgen's participation in the Medicaid program, Amgen entered into a rebate agreement with the Medicaid Program pursuant to 42 U.S.C. §1396r-8 under which Amgen agreed to pay the Medicaid Program quarterly rebates determined in part by "best price," which is defined as "the lowest price available from the manufacturer."

338. In particular, as part of the rebate agreement, Amgen agreed:

(a) It would determine best price, taking into account discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and would make quarterly rebates where necessary to bring the price down to the actual lowest price offered to any commercial entity.

(b) It would also determine its best price based upon average manufacturers price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid;" and,

(c) It would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price for that quarter, so long as the sale of a product at a nominal price was not contingent on any other sale.

339. After execution of its agreement, Amgen was supposed to report its "best price" in each quarter to the Medicaid program for each of its drugs. To increase market share through "marketing the spread" and otherwise, Amgen failed to report the best price for its drugs.

340. Through the above described acts and omissions, Amgen engaged in an artificial price inflation scheme. Pursuant to that scheme, Amgen did not report the actual "best price" or "average manufacturer's price" for its drugs, but instead (i) reported higher prices and (ii) excluded discounts and other inducements described herein offered to

hospitals and clinics that resulted in lower prices than the prices reported to the Medicaid Program.

341. Defendants thereby has violated 31 U.S.C. 3729(a)(7) in that, acting with the intent to defraud, Defendants knowingly made or used, or caused to be made or used, false records or statements to conceal, avoid or decrease Amgen's obligation to pay or transmit quarterly rebate payments to the United States Government – specifically – Amgen intentionally made false statements in quarterly Best Price Reports to CMS regarding the AMP for its drugs with the intent to decrease and/or avoid its quarterly rebate payment obligations to the Medicaid program.

342. As a result of Amgen's violations of its Rebate Agreement and 31 U.S.C. §3729(a)(7), the Medicaid program paid substantially higher prices for Amgen's drugs than it would have, and the Medicaid Program was deprived of its appropriate rebate as a result of Amgen's inaccurate reporting of best price.

343. It is believed that as a result of Defendants' violations of 27 U.S.C. §3729 (a)(7) the United States has been damaged in an amount far in excess of millions of dollars exclusive of interest. By reason of Defendants violations of 27 U.S.C. §3729 (a)(7), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendants.

344. Arriazola is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of herself and the United States.

COUNT FIVE
California False Claims Act
Ca. Government Code §12650 *et seq.*

345. Plaintiffs Arriazola and the State of California reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

346. This Count is brought by Arriazola in the name of the State of California under the *qui tam* provisions of the California False Claims Act, California Government Code §12651(a) pursuant to which treble damages and civil penalties are sought.

347. Cal. Gov't Code §12651(a) provides liability for the costs of a civil action, a civil penalty of up to $10,000 and treble damages for all damages sustained by the State for any person who-

(1) Knowingly presents, or causes to be presented, to an officer or employee of the State or of any political subdivision thereof, a false claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the State or any political subdivision;

(3) Conspires to defraud the State or any political subdivision by getting a false claim allowed or paid by the State or by any political subdivision;

(7) Knowingly makes, uses, or causes to be made or used a false record or statement or conceal, avoid, or decrease an obligation to pay or transmit money or property to the State; and/or,

(8) Is a beneficiary of an inadvertent submission of a false claim, and fails to disclose the false claim to the State or the political subdivision within a reasonable time after discovery of the false claim.

348. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code §650 and §650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code, §14107.2.

349. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of California. Amgen, at all times relevant to this action, has

operated and continues to operate pharmaceutical distribution facilities in the State of California.

350. Amgen violated Cal. Bus. Prof. Code §§650 and 650.1 and Calif. Welf. & Inst. Code §14107.2 from at least 1999 to the present by engaging in the fraudulent and illegal practices described herein with regard to Aranesp, Neulasta and other drugs.

351. By its violation of federal and state laws, including Cal. Bus. & Prof. Code §§650-650.1 and Cal. Welf. Inst. Code §14107.2, the Anti-Kickback Act, and Best Pricing Requirements, as described herein, Amgen further violated Cal. Govt. Code §12651(a) (1), (2), (3), (7) and (8).

352. Specifically, Amgen has:

- Caused hundreds of thousands of false claims to be presented to the State of California,
- Knowingly made, used or caused to be made or used false records to get false claims paid,
- Conspired to defraud the State by getting false and fraudulent claims allowed or paid;
- Knowingly made, used or caused to be made or used a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State; and,
- Failed to disclose the existence of the false claims it has caused to be presented.

353. Amgen has violated Cal. Govt. Code §12651(a) (1), (2), (3), (7) and (8) knowingly, as that term is defined by the California False Claims Act.

354. The State of California, by and through the California Medicaid Program and other State health care programs, and unaware if Amgen's illegal practices, paid the claims and has sustained damages because of these acts of the Defendants.

355. Compliance with the applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of California in connection with Amgen's illegal practices.

356. Had the State of California known that Amgen was violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers in connection with Amgen's illegal practices.

357. The amounts of the false or fraudulent claims caused to be made to the State of California and paid by the State were material. It is believed that as a result of Amgen's violations of Cal. Gov't Code §12651(a) – including (a) (1), (2), (3) and (8) – the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

358. Arriazola is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code §12652(c) on behalf of herself and the State of California.

359. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

COUNT SIX
Delaware False Claims and Reporting Act
6 Del. C. §1201(a)(2)

360. Plaintiffs Arriazola and the State of Delaware reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

361. This is a *qui tam* action brought by Arriazola and the State of Delaware to recover treble damages, civil penalties and the cost of this action, under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

362. The Delaware False Claims and Reporting Act, Del. Code, Ann. Tit. 6, §1201(a)(2) provides for liability for any person who:

> Knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; ….shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus three (3) times the amount of the actual damages which the Government sustains because of the act of that person.

Id.

363. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with this law is a condition precedent for reimbursement under the Delaware Medicaid and other state funded health programs.

364. Defendants violated 31 Del. C. § 1005 from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

365. Defendants further violated 6 Del. C. §1201 (a)(2) by making or using or causing to be made or used, directly or indirectly, false records and/or statements to get false and fraudulent claims paid and approved by the State of Delaware.

366. Compliance with the applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and

belief also an express condition, of payment of claims submitted to the State of Delaware in connection with Defendants' fraudulent and illegal practices.

367. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

368. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Delaware but for the illegal practices of Defendants described in this complaint.

369. Had the State of Delaware known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

370. As a result of Defendants' violations of 6 Del. C. §1201(a)(2), the State of Delaware has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

371. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to 6 Del. C. §1203(b) on behalf of herself and the State of Delaware.

372. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

COUNT SEVEN
Delaware False Claims and Reporting Act
6 Del. C. §1201(a)(1)

373. Plaintiffs Arriazola and the State of Delaware reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

374. This is a *qui tam* action brought by Arriazola and the State of Delaware to recover treble damages, civil penalties and the cost of this action, under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

375. The Delaware False Claims and Reporting Act, Del. Code, Ann. Tit. 6, §1201(a)(1) provides for liability for any person who:

> Knowingly presents or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus three (3) times the amount of the actual damages which the Government sustains because of the act of that person.

Id.

376. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with this law is a condition precedent for reimbursement under the Delaware Medicaid and other state funded health programs.

377. Defendants violated 31 Del. C. § 1005 from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

378. Defendants further violated 6 Del. C. §1201(a) by presenting or causing to be presented, directly or indirectly, to the Delaware Medicaid Program false and fraudulent

claims for payment and approval, claims which failed to disclose or actively concealed the material violations of the state and federal law as set forth herein.

379. Compliance with the applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and belief, also an express condition, of payment of claims submitted to the State of Delaware in connection with Defendants' fraudulent and illegal practices.

380. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

381. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Delaware but for the illegal practices of Defendants described in this complaint.

382. Had the State of Delaware known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

383. As a result of Defendants' violations of 6 Del. C. §1201(a)(1), the State of Delaware has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

384. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to 6 Del. C. §1203(b) on behalf of herself and the State of Delaware.

385. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

COUNT EIGHT
Delaware False Claims and Reporting Act
6 Del. C. §1201(a)(3)

386. Plaintiffs Arriazola and the State of Delaware reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

387. Plaintiffs Arriazola and the State of Delaware reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

388. This is a qui tam action brought by Arriazola and the State of Delaware to recover treble damages, civil penalties and the cost of this action, under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

389. The Delaware False Claims and Reporting Act, Del. Code, Ann. Tit. 6, §1201(a)(3) provides for liability for any person who:

> Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus three (3) times the amount of the actual damages which the Government sustains because of the act of that person.

Id.

390. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with this law is a condition precedent for reimbursement under the Delaware Medicaid and other state funded health programs.

391. Defendants violated 31 Del. C. § 1005 from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

392. Defendants further violated 6 Del. C. §1201(a) by conspiring to defraud the State of Delaware by getting false and fraudulent claims allowed and paid.

393. Compliance with the applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and belief, also an express condition, of payment of claims submitted to the State of Delaware in connection with Defendants' fraudulent and illegal practices.

394. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

395. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Delaware but for the illegal practices of Defendants described in this complaint.

396. Had the State of Delaware known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

397. As a result of Defendants' violations of 6 Del. C. §1201(a)(3), the State of Delaware has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

398. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to 6 Del. C. §1203(b) on behalf of herself and the State of Delaware.

399. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program

COUNT NINE
Delaware False Claims and Reporting Act
6 Del. C. §1201(a)(7)

400. Plaintiffs Arriazola and the State of Delaware reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

401. This is a qui tam action brought by Arriazola and the State of Delaware to recover treble damages, civil penalties and the cost of this action, under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

402. The Delaware False Claims and Reporting Act, Del. Code, Ann. Tit. 6, §1201(a)(7) provides for liability for any person who:

> Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus three (3) times the amount of the actual damages which the Government sustains because of the act of that person.

Id.

403. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with this law is a condition precedent for reimbursement under the Delaware Medicaid and other state funded health programs.

404. Defendants violated 31 Del. C. § 1005 from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

405. Defendants further violated 6 Del. C. §1201(a) by presenting or causing to be presented, directly or indirectly, to the Delaware Medicaid Program false and fraudulent claims for payment and approval, claims which failed to disclose or actively concealed the material violations of the state and federal law as set forth herein.

406. Compliance with the applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and belief, also an express condition, of payment of claims submitted to the State of Delaware in connection with Defendants' fraudulent and illegal practices.

407. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

408. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Delaware but for the illegal practices of Defendants described in this complaint.

409. Had the State of Delaware known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

410. As a result of Defendants' violations of 6 Del. C. §1201(a)(7), the State of Delaware has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

411. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to 6 Del. C. §1203(b) on behalf of herself and the State of Delaware.

412. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

COUNT TEN
District of Columbia False Claims Act
D.C. Code Ann. § 2-308.14(a)(1)

413. Plaintiffs Arriazola and the State of District of Columbia reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

414. This is a *qui tam* action brought by Arriazola and the District of Columbia to recover treble damages, civil penalties and the cost of this action, under the District of Columbia Procurement Reform Amendment Act, D.C. Code §2-308.14 *et seq.*

415. The District of Columbia Procurement Reform Amendment Act, D.C. Code §2-308.14(a)(1), specifically provides in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for the costs of a civil action brought to recover penalties or damages and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval.

416. In addition, D.C. Code §4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

(1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program; or

(2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

417. Defendants violated D.C. Code §4-802(c) from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

418. Defendants further violated D.C. Code §2-308.14(a)(1) by knowingly presenting and causing to be presented false claims for payment or approval.

419. Compliance with the applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and belief, also an express condition, of payment of claims submitted to the District of Columbia in connection with Defendants' fraudulent and illegal practices.

420. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

421. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of District of Columbia but for the illegal practices of Defendants described in this complaint.

422. Had the District of Columbia known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

423. As a result of Defendants' violations of D.C. Code §2-308.14(a)(1), the State of Delaware has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

424. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to D.C. Code §2-308.15(b) on behalf of herself and the District of Columbia.

425. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

COUNT ELEVEN
District of Columbia False Claims Act
D.C. Code Ann. § 2-308.14(a)(2)

426. Plaintiffs Arriazola and the State of District of Columbia reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

427. This is a *qui tam* action brought by Arriazola and the District of Columbia to recover treble damages, civil penalties and the cost of this action, under the District of Columbia Procurement Reform Amendment Act, D.C. Code §2-308.14 *et seq.*

428. The District of Columbia Procurement Reform Amendment Act, D.C. Code §2-308.14(a)(2), specifically provides in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for the costs of a civil action brought to recover penalties or damages and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District.

429. In addition, D.C. Code §4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

(1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program; or

(2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

430. Defendants violated D.C. Code §4-802(c) from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

431. Defendants further violated D.C. Code §2-308.14(a)(2) by knowingly making or using or causing to be made or used false records or statements to get a false claim paid by the District.

432. Compliance with the applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and belief, also an express condition, of payment of claims submitted to the District of Columbia in connection with Defendants' fraudulent and illegal practices.

433. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

434. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the District of Columbia but for the illegal practices of Defendants described in this complaint.

435. Had the District of Columbia known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

436. As a result of Defendants' violations of D.C. Code §2-308.14(a)(2), the District of Columbia has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

437. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to D.C. Code §2-308.15(b) on behalf of herself and the District of Columbia.

438. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

COUNT TWELVE
District of Columbia False Claims Act
D.C. Code Ann. § 2-308.14(a)(3)

439. Plaintiffs Arriazola and the State of District of Columbia reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

440. This is a *qui tam* action brought by Arriazola and the District of Columbia to recover treble damages, civil penalties and the cost of this action, under the District of Columbia Procurement Reform Amendment Act, D.C. Code §2-308.14 *et seq.*

441. The District of Columbia Procurement Reform Amendment Act, D.C. Code §2-308.14(a)(2), specifically provides in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for the costs of a civil action brought to recover penalties or damages and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:

(3) Conspires to defraud the District of Columbia by getting a false claim allowed or paid by the District.

442. In addition, D.C. Code §4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

(1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program; or

(2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

443. Defendants violated D.C. Code §4-802(c) from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

444. Defendants further violated D.C. Code §2-308.14(a)(3) by conspiring to get false and fraudulent claims allowed and paid by the District.

445. Compliance with the applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and belief, also an express condition, of payment of claims submitted to the District of Columbia in connection with Defendants' fraudulent and illegal practices.

446. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

447. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the District of Columbia but for the illegal practices of Defendants described in this complaint.

448. Had the District of Columbia known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

449. As a result of Defendants' violations of D.C. Code §2-308.14(a)(3), the District of Columbia has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

450. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to D.C. Code §2-308.15(b) on behalf of herself and the District of Columbia.

451. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

COUNT THIRTEEN
District of Columbia False Claims Act
D.C. Code Ann. § 2-308.14(a)(7)

452. Plaintiffs Arriazola and the State of District of Columbia reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

453. This is a qui tam action brought by Arriazola and the District of Columbia to recover treble damages, civil penalties and the cost of this action, under the District of Columbia Procurement Reform Amendment Act, D.C. Code §2-308.14 *et seq.*

454. The District of Columbia Procurement Reform Amendment Act, D.C. Code §2-308.14(a)(7), specifically provides in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act

of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for the costs of a civil action brought to recover penalties or damages and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:

(1) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government.

455. In addition, D.C. Code §4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

(1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program; or

(2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

456. Defendants violated D.C. Code §4-802(c) from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

457. Defendants further violated D.C. Code §2-308.14(a)(7) by making, using or causing to be made or used a false record or statement to conceal their illegal conduct and to avoid or decrease their obligations to pay or transmit money to the District.

458. Compliance with the applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and belief, also an express condition, of payment of claims submitted to the District of Columbia in connection with Defendants' fraudulent and illegal practices.

459. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

460. For example, claims for reimbursement for off-label prescriptions of

Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the District of Columbia but for the illegal practices of Defendants described in this complaint.

461. Had the District of Columbia known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

462. As a result of Defendants' violations of D.C. Code §2-308.14(a)(7), the District of Columbia has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

463. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to D.C. Code §2-308.15(b) on behalf of herself and the District of Columbia.

464. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program

COUNT FOURTEEN
Florida False Claims Act
Fl. Stat. §§68.081-68.09

465. Plaintiffs Arriazola and the State of Florida reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

466. This Count is brought by Arriazola on behalf of the State of Florida under the *qui tam* provisions of Florida False Claims Act, Fl. Stat. §§68.081-68.09 to recover treble damages and civil penalties.

467. Fla. Stat §68.082(2)(a) provides liability for any person who-

> Knowingly presents, or causes to be presented, to an officer or employee of an agency, a false or fraudulent claim for payment or approval; ...is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

468. In addition, Fla. Stat. §409.920 makes it a crime to:

> Knowingly charge, solicit, accept or receive anything of value, other then an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source.
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> Knowingly solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, or for recommending, obtaining, purchasing, leasing or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

469. Fla. Stat. §456.054(2) also prohibits the offering, payment solicitation, or receipt of a kickback to a health care provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

470. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Florida.

471. Defendants violated Fla. Stat. §§ 409.920(c) and (e) and §456.054(2) from at least 1998 to the present by engaging in the illegal practices described herein.

472. Defendants further violated Fla. Stat §68.082(2)(a) by presenting or causing to be presented a false claim for payment or approval as well as by their violations of federal and Florida state laws including Fla. Stat §456.054(2), the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

473. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Florida in connection with Amgen's illegal practices.

474. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

475. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Florida but for the illegal practices of Defendants described in this complaint.

476. Had the State of Florida known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

477. As a result of Defendants' violations of Fla. Stat. §68.083(2), the State of Florida has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

478. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Fla. Stat. §68.083(2) on behalf of herself and the State of Florida.

479. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

COUNT FIFTEEN
Florida False Claims Act
Fl. Stat. §§68.081-68.09

480. Plaintiffs Arriazola and the State of Florida reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

481. This Count is brought by Arriazola on behalf of the State of Florida under the *qui tam* provisions of Florida False Claims Act, Fl. Stat. §§68.081-68.09 to recover treble damages and civil penalties.

482. Fla. Stat §68.082(2)(b) provides liability for any person who-

> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;... is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

483. In addition, Fla. Stat. §409.920 makes it a crime to:

> Knowingly charge, solicit, accept or receive anything of value, other then an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source.
>
> * * *
>
> Knowingly solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, or for recommending, obtaining, purchasing, leasing or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

484. Fla. Stat. §456.054(2) also prohibits the offering, payment solicitation, or receipt of a kickback to a health care provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

485. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Florida.

486. Defendants violated Fla. Stat. §§ 409.920(c) and (e) and §456.054(2) from at least 1998 to the present by engaging in the illegal practices described herein.

487. Defendants further violated Fla. Stat §68.082(2)(b) by presenting or causing to be presented a false claim for payment or approval as well as by their violations of federal and Florida state laws including Fla. Stat §456.054(2), the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

488. Compliance with the applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Florida in connection with Amgen's illegal practices.

489. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

490. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Florida but for the illegal practices of Defendants described in this complaint.

491. Had the State of Florida known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

492. As a result of Defendants' violations of Fla. Stat. §68.083(2), the State of Florida has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

493. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Fla. Stat §68.083(2) on behalf of herself and the State of Florida.

494. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

COUNT SIXTEEN
Florida False Claims Act
Fl. Stat. §§68.081-68.09

495. Plaintiffs Arriazola and the State of Florida reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

496. This Count is brought by Arriazola on behalf of the State of Florida under the *qui tam* provisions of Florida False Claims Act, Fl. Stat. §§68.081-68.09 to recover treble damages and civil penalties.

497. Fla. Stat §68.082(2)(c) provides liability for any person who-

> Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid; ...is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

498. In addition, Fla. Stat. §409.920 makes it a crime to:

> Knowingly charge, solicit, accept or receive anything of value, other then an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency

or its fiscal agent for any payment received from a third-party source.

* * *

> Knowingly solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, or for recommending, obtaining, purchasing, leasing or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

499. Fla. Stat. §456.054(2) also prohibits the offering, payment solicitation, or receipt of a kickback to a health care provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

500. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Florida.

501. Defendants violated Fla. Stat. §§ 409.920(c) and (e) and §456.054(2) from at least 1998 to the present by engaging in the illegal practices described herein.

502. Defendants further violated Fla. Stat §68.082(2)(c) conspiring to defraud the State of Florida by getting false claims paid as well as by their violations of federal and Florida state laws including Fla Stat §456.054(2), the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

503. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Florida in connection with Amgen's illegal practices.

504. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been

submitted to the State of Florida but for the illegal practices of Defendants described in this complaint.

505. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

506. Had the State of Florida known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

507. As a result of Defendants' violations of Fla. Stat. §68.083(2), the State of Florida has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

508. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Fla. Stat. §68.083(2) on behalf of herself and the State of Florida.

509. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

COUNT SEVENTEEN
Florida False Claims Act
Fl. Stat. §§68.081-68.09

510. Plaintiffs Arriazola and the State of Florida reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

511. This Count is brought by Arriazola on behalf of the State of Florida under the *qui tam* provisions of Florida False Claims Act, Fl. Stat. §§68.081-68.09 to recover treble damages and civil penalties.

512. Fla. Stat §68.082(2)(g) provides liability for any person who-

> Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to an agency… is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

513. In addition, Fla. Stat. §409.920 makes it a crime to:

> Knowingly charge, solicit, accept or receive anything of value, other then an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source.
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> * * *
>
> Knowingly solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, or for recommending, obtaining, purchasing, leasing or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

514. Fla. Stat. §456.054(2) also prohibits the offering, payment solicitation, or receipt of a kickback to a health care provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

515. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Florida.

516. Defendants violated Fla. Stat. §§ 409.920(c) and (e) and §456.054(2) from at least 1998 to the present by engaging in the illegal practices described herein.

517. Defendants further violated Fla. Stat §68.082(2)(g) by making, using or causing to be made or used false records or statements to conceal their actions and to avoid or decrease their obligation to pay or transmit money to the State of Florida as well as

through their violations of federal and Florida state laws including Fla Stat §456.054(2), the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

518. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Florida in connection with Amgen's illegal practices.

519. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

520. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Florida but for the illegal practices of Defendants described in this complaint.

521. Had the State of Florida known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

522. As a result of Defendants' violations of Fla. Stat. §68.083(2), the State of Florida has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

523. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Fla. Stat. §68.083(2) on behalf of herself and the State of Florida.

524. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

COUNT EIGHTEEN
Georgia False Medicaid Claims Act
O.C.G.A. § 49-4-168.1 *et seq.*

525. Plaintiffs Arriazola and the State of Georgia reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

526. This Count is brought by Arriazola on behalf of the State of Georgia under the *qui tam* provisions of the Georgia State False Medicaid Claims Act, 49-4-168, *et seq*, specifically provides, in part at 49-4-168.1, that:

> (a) Any person who:
>
> (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval…shall be liable to the State of Georgia for a civil penalty of not less than $5,500 and not more than $11,000 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

527. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Georgia.

528. Defendants violated Official Code of Code of Georgia Annotated, 49-4-168(a)(1) by presenting or causing to be presented false or fraudulent claims for payment or approval to the State of Georgia as well as through their violations of federal and Georgia state laws, including the Anti-Kickback Act and Best Pricing Requirements, as described herein.

529. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and

belief an express condition, of payment of claims submitted to the State of Georgia in connection with Amgen's illegal practices.

530. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

531. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Georgia but for the illegal practices of Defendants described in this complaint.

532. Had the State of Georgia known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

533. As a result of Defendants' violations of Official Code of Georgia Annotated, 49-4-168, *et seq.*, the State of Georgia has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

534. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Official Code of Georgia Annotated, 49-4-168, *et seq.* on behalf of herself and the State of Georgia.

535. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

COUNT NINETEEN
Georgia False Medicaid Claims Act
O.C.G.A. § 49-4-168.1 *et seq.*

536. Plaintiffs Arriazola and the State of Georgia reallege and incorporate by

reference each and every of the foregoing paragraphs as if fully set forth herein.

537. This Count is brought by Arriazola on behalf of the State of Georgia under the *qui tam* provisions of the Georgia State False Medicaid Claims Act, 49-4-168, *et seq*, specifically provides, in part at 49-4-168.1, that:

(a) Any person who:

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program…shall be liable to the State of Georgia for a civil penalty of not less than $5,500 and not more than $11,000 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

538. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Georgia.

539. Defendants violated Official Code of Code of Georgia Annotated, 49-4-168(a)(2) by making or using or causing to be made or used false records or statements to get false or fraudulent claims paid or allowed by State of Georgia as well as through their violations of federal and Georgia state laws, including the Anti-Kickback Act and Best Pricing Requirements, as described herein.

540. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Georgia in connection with Amgen's illegal practices.

541. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

542. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been

submitted to the State of Georgia but for the illegal practices of Defendants described in this complaint.

543. Had the State of Georgia known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

544. As a result of Defendants' violations of Official Code of Georgia Annotated, 49-4-168, *et seq.*, the State of Georgia has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

545. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Official Code of Georgia Annotated, 49-4-168, *et seq.* on behalf of herself and the State of Georgia.

546. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

COUNT TWENTY
Georgia False Medicaid Claims Act
O.C.G.A. § 49-4-168.1 *et seq.*

547. Plaintiffs Arriazola and the State of Georgia reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

548. This Count is brought by Arriazola on behalf of the State of Georgia under the *qui tam* provisions of the Georgia State False Medicaid Claims Act, 49-4-168, *et seq.*

549. The Georgia State False Medicaid Claims Act specifically provides, in part at 49-4-168.1, that:

(a) Any person who:

> (3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid…shall be liable to the State of Georgia for a civil penalty of not less than $5,500 and not more than $11,000 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

550. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Georgia.

551. Defendants violated Official Code of Georgia Annotated, 49-4-168(a)(3) by conspiring to defraud the State of Georgia Medicaid program by getting false or fraudulent claims allowed or paid as well as through their violations of federal and Georgia state laws, including the Anti-Kickback Act and Best Pricing Requirements, as described herein.

552. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Georgia in connection with Amgen's illegal practices.

553. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

554. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Georgia but for the illegal practices of Defendants described in this complaint.

555. Had the State of Georgia known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

556. As a result of Defendants' violations of Official Code of Georgia Annotated, 49-4-168, *et seq.*, the State of Georgia has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

557. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Official Code of Georgia Annotated, 49-4-168, *et seq.* on behalf of herself and the State of Georgia.

558. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

COUNT TWENTY-ONE
Georgia False Medicaid Claims Act
O.C.G.A. § 49-4-168.1 *et seq.*

559. Plaintiffs Arriazola and the State of Georgia reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

560. This Count is brought by Arriazola on behalf of the State of Hawaii under the *qui tam* provisions of the Georgia State False Medicaid Claims Act, 49-4-168, *et seq.*, specifically provides in pertinent parts at 49-4-168.1(a)(4) and (7) that any person who engages in the following conduct shall be liable to the State of Georgia for a civil penalty of not less than $5,500 and not more than $11,000 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person:

> (4) Has possession, custody or control of property or money used, or to be used by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person received a certificate of receipt; or

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay or transmit money or property to the State of Georgia…

561. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Georgia.

562. Defendants violated Official Code of Code of Georgia Annotated, 49-4-168(a)(4) and (7) by making, using or causing to be made or used false records or statements to conceal their actions and to avoid or decrease their obligation to pay or transmit money to the State of Florida as well as through their violations of federal and Georgia state laws, including the Anti-Kickback Act and Best Pricing Requirements, as described herein.

563. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Georgia in connection with Amgen's illegal practices.

564. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

565. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Georgia but for the illegal practices of Defendants described in this complaint.

566. Had the State of Georgia known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

567. As a result of Defendants' violations of Official Code of Georgia Annotated, 49-4-168, *et seq.*, the State of Georgia has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

568. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Official Code of Georgia Annotated, 49-4-168, *et seq.* on behalf of herself and the State of Georgia.

569. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

COUNT TWENTY-TWO
Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)(1)

570. Plaintiffs Arriazola and the State of Hawaii reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

571. This Count is brought by Arriazola on behalf of the State of Hawaii under the *qui tam* provisions of the Hawaii False Claims Act, Haw. Rev. Stat §661-21(a)(1).

572. The Hawaii False Claims Act, Haw. Rev. Stat §661-21 specifically provides, in part, that any person who:

> (1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;...
>
> Shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three (3) times the amount of damages that the State sustains due to the act of that person.

573. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Hawaii.

574. Defendants violated Haw. Rev. Stat. §661-21(a) by presenting or causing

to be presented false claims for payment or approval to the State of Hawaii Medicaid program.

575. Defendants further violated Haw. Rev. Stat. §661-21(a) and knowingly caused hundreds of thousands of false claims to be presented to the State of Hawaii from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

576. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Hawaii in connection with Defendants' illegal practices.

577. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

578. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Hawaii but for the illegal practices of Defendants described in this complaint.

579. Had the State of Hawaii known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

580. As a result of Defendants' violations of Haw. Rev. Stat. §661-21(a), the State of Hawaii has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

581. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Haw. Rev. Stat. §661-25(a) on behalf of herself and the State of Hawaii.

582. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

COUNT TWENTY-THREE
Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)(2)

583. Plaintiffs Arriazola and the State of Hawaii reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

584. This Count is brought by Arriazola on behalf of the State of Hawaii under the *qui tam* provisions of the Hawaii False Claims Act, Haw. Rev. Stat §661-21 *et seq.*

585. The Hawaii False Claims Act, Haw. Rev. Stat §661-21 (a)(2), specifically provides, in part, that any person who:

> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;...
>
> Shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three (3) times the amount of damages that the State sustains due to the act of that person.

586. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Hawaii.

587. Defendants violated Haw. Rev. Stat. §661-21(a) by making or using or causing to be made or used false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii Medicaid program.

588. Defendants further violated Haw. Rev. Stat. §661-21(a) and knowingly

caused hundreds of thousands of false claims to be presented to the State of Hawaii from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

589. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Hawaii in connection with Defendants' illegal practices.

590. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

591. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Hawaii but for the illegal practices of Defendants described in this complaint.

592. Had the State of Hawaii known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

593. As a result of Defendants' violations of Haw. Rev. Stat. §661-21(a), the State of Hawaii has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

594. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Haw. Rev. Stat. §661-25(a) on behalf of herself and the State of Hawaii.

595. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

COUNT TWENTY-FOUR
Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)(3)

596. Plaintiffs Arriazola and the State of Hawaii reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

597. This Count is brought by Arriazola on behalf of the State of Hawaii under the *qui tam* provisions of the Hawaii False Claims Act, Haw. Rev. Stat §661-21 *et seq.*

598. The Hawaii False Claims Act, Haw. Rev. Stat §661-21 (a)(3), specifically provides, in part, that any person who:

> (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;...
>
> Shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three (3) times the amount of damages that the State sustains due to the act of that person.

599. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Hawaii.

600. Defendants violated Haw. Rev. Stat. §661-21(a) by conspiring to defraud the State of Hawaii by getting a false or fraudulent claim paid or allowed by the State of Hawaii Medicaid program.

601. Defendants further violated Haw. Rev. Stat. §661-21(a) and knowingly caused hundreds of thousands of false claims to be presented to the State of Hawaii from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

602. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Hawaii in connection with Defendants' illegal practices.

603. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

604. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Hawaii but for the illegal practices of Defendants described in this complaint.

605. Had the State of Hawaii known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

606. As a result of Defendants' violations of Haw. Rev. Stat. §661-21(a), the State of Hawaii has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

607. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Haw. Rev. Stat. §661-25(a) on behalf of herself and the State of Hawaii.

608. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

COUNT TWENTY-FIVE
Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)(7)

609. Plaintiffs Arriazola and the State of Hawaii reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

610. This Count is brought by Arriazola on behalf of the State of Hawaii under the *qui tam* provisions of the Hawaii False Claims Act, Haw. Rev. Stat §661-21 *et seq.*

611. The Hawaii False Claims Act, Haw. Rev. Stat §661-21 (a)(7), specifically provides, in part, that any person who:

> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State…
>
> Shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three (3) times the amount of damages that the State sustains due to the act of that person.

612. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Hawaii.

613. Defendants violated Haw. Rev. Stat. §661-21(a)(7) by making, using or causing to be made or used false records or statements to conceal their actions and to avoid or decrease their obligation to pay or transmit money to the State of Hawaii.

614. Defendants further violated Haw. Rev. Stat. §661-21(a) and knowingly caused hundreds of thousands of false claims to be presented to the State of Hawaii from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

615. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and

belief an express condition, of payment of claims submitted to the State of Hawaii in connection with Defendants' illegal practices.

616. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

617. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Hawaii but for the illegal practices of Defendants described in this complaint.

618. Had the State of Hawaii known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

619. As a result of Defendants' violations of Haw. Rev. Stat. §661-21(a), the State of Hawaii has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

620. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Haw. Rev. Stat. §661-25(a) on behalf of herself and the State of Hawaii.

621. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

COUNT TWENTY-SIX
Illinois Whistleblower Reward and Protection Act[6]
740 Ill. Comp. Stat. §175/3(a)(1)

622. Plaintiffs Arriazola and the State of Illinois reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

623. This Count is brought by Arriazola on behalf of the State of Illinois under the *qui tam* provisions of the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175 *et seq.*

624. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175 (a)(1), specifically provides, in part, that any person who:

> (1) Knowingly presents, or causes to be presented, to an officer or employee of the State or member of the Guard a false or fraudulent claim for payment or approval;...
>
> is liable to State for civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

625. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

626. Defendants violated 305 ILCS 5/8A-3(b) from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

[6] In July 2010, an amendment re-titled this statute the Illinois False Claims Act. See 2010 Ill. Legis. Serv. 96-1304. The amendment made other changes to the act as well, but none of those changes are relevant here.

627. Defendants further violated 740 ILCS 175/3(a)(1) by knowingly presenting or causing to be presented false or fraudulent claims for payment or approval to the State of Illinois Medicaid program.

628. Defendants further violated 740 ILCS 175/3(a)(1) and knowingly caused hundreds of thousands of false claims to be presented to the State of Illinois from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

629. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Illinois in connection with Defendants' illegal practices.

630. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

631. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Illinois but for the illegal practices of Defendants described in this complaint.

632. Had the State of Illinois known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

633. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

634. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of herself and the State of Illinois.

635. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

COUNT TWENTY-SEVEN
Illinois Whistleblower Reward and Protection Act[7]
740 Ill. Comp. Stat. § 175/3(a)(2)

636. Plaintiffs Arriazola and the State of Illinois reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

637. This Count is brought by Arriazola on behalf of the State of Illinois under the *qui tam* provisions of the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175 *et seq.*

638. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175 (a)(1), specifically provides, in part, that any person who:

> (2) Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;...
>
> is liable to State for civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

639. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in

[7] In July 2010, an amendment re-titled this statute the Illinois False Claims Act. See 2010 Ill. Legis. Serv. 96-1304. The amendment made other changes to the act as well, but none of those changes are relevant here.

return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

640. Defendants violated 305 ILCS 5/8A-3(b) from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

641. Defendants further violated 740 ILCS 175/3(a)(2) by making or using or causing to be made or used false records or statements to get false or fraudulent claims paid or approved by the State of Illinois Medicaid program.

642. Defendants further violated 740 ILCS 175/3(a)(1) and knowingly caused hundreds of thousands of false claims to be presented to the State of Illinois from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

643. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Hawaii in connection with Defendants' illegal practices.

644. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

645. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Illinois but for the illegal practices of Defendants described in this complaint.

646. Had the State of Illinois known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

647. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

648. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of herself and the State of Illinois.

649. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

COUNT TWENTY-EIGHT
Illinois Whistleblower Reward and Protection Act[8]
740 Ill. Comp. Stat. § 175/3(a)(3)

650. Plaintiffs Arriazola and the State of Illinois reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

651. This Count is brought by Arriazola on behalf of the State of Illinois under the *qui tam* provisions of the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175 *et seq.*

652. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175 (a)(3), specifically provides, in part, that any person who:

> (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;...

[8] In July 2010, an amendment re-titled this statute the Illinois False Claims Act. See 2010 Ill. Legis. Serv. 96-1304. The amendment made other changes to the act as well, but none of those changes are relevant here.

> is liable to State for civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

653. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

654. Defendants violated 305 ILCS 5/8A-3(b) from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

655. Defendants further violated 740 ILCS 175/3(a)(3) by conspiring to defraud the State of Illinois by getting false or fraudulent claims paid or allowed.

656. Defendants further violated 740 ILCS 175/3(a)(3) and knowingly caused hundreds of thousands of false claims to be presented to the State of Illinois from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

657. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Hawaii in connection with Defendants' illegal practices.

658. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

659. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been

submitted to the State of Illinois but for the illegal practices of Defendants described in this complaint.

660. Had the State of Illinois known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

661. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

662. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of herself and the State of Illinois.

663. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

COUNT TWENTY-NINE
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. § 175/3(a)(7)[9]

664. Plaintiffs Arriazola and the State of Illinois reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

665. This Count is brought by Arriazola on behalf of the State of Illinois under the *qui tam* provisions of the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175 *et seq.*

666. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp.

[9] In July 2010, an amendment re-titled this statute the Illinois False Claims Act. See 2010 Ill. Legis. Serv. 96-1304. The amendment made other changes to the act as well, but none of those changes are relevant here.

Stat. §175 (a)(1), specifically provides, in part, that any person who:

> (4) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State;…
>
> is liable to State for civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

667. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

668. Defendants violated 305 ILCS 5/8A-3(b) from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

669. Defendants further violated 740 ILCS 175/3(a)(7) by making, using or causing to be made or used false records or statements to conceal their actions and to avoid or decrease their obligation to pay or transmit money to the State of Illinois.

670. Defendants further violated 740 ILCS 175/3(a)(7) and knowingly caused hundreds of thousands of false claims to be presented to the State of Illinois from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

671. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Illinois in connection with Defendants' illegal practices.

672. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

673. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Illinois but for the illegal practices of Defendants described in this complaint.

674. Had the State of Illinois known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

675. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

676. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of herself and the State of Illinois.

677. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

COUNT THIRTY
Indiana False Claims and Whistleblower Protection Act
Ind. Code § 5-11-5.5-2(b)(1) and (8)

678. Plaintiffs Arriazola and the State of Indiana reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

679. This Count is brought by Arriazola on behalf of the State of Indiana under

the *qui tam* provisions of the Indiana False Claims and Whistleblower Act, IC 5-11-5.5 and pursuant to that Act seeks recovery of civil penalties, treble damages and the cost of the civil action.

680. The Indiana False Claims and Whistleblower Act, IC 5-11-5.5-2(b) (2005), specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for civil penalties and three times the amount of damages that the State sustains because of the act of that person, including:

(1) Presents a false claim to the State for payment or approval; or
(8) Causing or inducing another person to perform an act described above.

681. Defendants violated Indiana False Claims and Whistleblower Act, IC 5-11-5.5 by presenting false claims to the State for payment or approval or cuasing to be presented false claims to the State for payment or approval.

682. Defendants further violated Indiana False Claims and Whistleblower Act, IC 5-11-5.5 and knowingly and intentionally caused hundreds of thousands of false claims to be presented to the State of Indiana from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

683. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Indiana in connection with Defendants' illegal practices.

684. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

685. For example, claims for reimbursement for off-label prescriptions of

Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Indiana but for the illegal practices of Defendants described in this complaint.

686. Had the State of Indiana known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

687. As a result of Defendants' violations of IC 5-11-5.5, the State of Indiana has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

688. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to 740 IC 5-11-5.5 on behalf of herself and the State of Indiana.

689. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

COUNT THIRTY-ONE
Indiana False Claims and Whistleblower Protection Act
Ind. Code § 5-11-5.5-2(b)(2)

690. Plaintiffs Arriazola and the State of Indiana reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

691. This Count is brought by Arriazola on behalf of the State of Indiana under the *qui tam* provisions of the Indiana False Claims and Whistleblower Act, IC 5-11-5.5 and pursuant to that Act seeks recovery of civil penalties, treble damages and the cost of the civil action.

692. The Indiana False Claims and Whistleblower Act, IC 5-11-5.5-2(b)

(2005), specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the State for civil penalties and three times the amount of damages that the State sustains because of the act of that person, including:

> (2) Makes or uses a false record or statement to obtain payment or approval of a false claim from the State; or
>
> (8) Causing or inducing another person to perform an act described above.

693. Defendants violated Indiana False Claims and Whistleblower Act, IC 5-11-5.5 by making or using false records or statements to obtain payment or approval of a false claim from the State of Indiana through its Medicaid program or causing to be made or used false records or statements to obtain payment or approval of a false claim from the State of Indiana through its Medicaid program

694. Defendants further violated Indiana False Claims and Whistleblower Act, IC 5-11-5.5 and knowingly and intentionally caused hundreds of thousands of false claims to be presented to the State of Indiana from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

695. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Indiana in connection with Defendants' illegal practices.

696. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

697. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been

submitted to the State of Indiana but for the illegal practices of Defendants described in this complaint.

698. Had the State of Indiana known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

699. As a result of Defendants' violations of IC 5-11-5.5, the State of Indiana has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

700. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to IC 5-11-5.5 on behalf of herself and the State of Indiana.

701. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

COUNT THIRTY-TWO
Indiana False Claims and Whistleblower Protection Act
Ind. Code § 5-11-5.5-2(b)(2)

702. Plaintiffs Arriazola and the State of Indiana reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

703. This Count is brought by Arriazola on behalf of the State of Indiana under the *qui tam* provisions of the Indiana False Claims and Whistleblower Act, IC 5-11-5.5 and pursuant to that Act seeks recovery of civil penalties, treble damages and the cost of the civil action.

704. The Indiana False Claims and Whistleblower Act, IC 5-11-5.5-2(b) (2005), specifically provides, in part, that by certain acts a person commits an unlawful

act and shall be liable to the State for civil penalties and three times the amount of damages that the State sustains because of the act of that person, including:

(7) Conspires with another person to perform an act described above; or

(8) Causes or induces another person to perform an act described above

705. Defendants violated Indiana False Claims and Whistleblower Act, IC 5-11-5.5 by conspiring to present or caused to be presented false claims for payment or approval and/or using or making or causing to be made or used false records or statements to get false claims paid by the State of Indiana through its Medicaid program.

706. Defendants further violated Indiana False Claims and Whistleblower Act, IC 5-11-5.5 and knowingly and intentionally caused hundreds of thousands of false claims and/or records to be presented to the State of Indiana from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

707. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Indiana in connection with Defendants' illegal practices.

708. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Indiana but for the illegal practices of Defendants described in this complaint.

709. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

710. Had the State of Indiana known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

711. As a result of Defendants' violations of IC 5-11-5.5, the State of Indiana has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

712. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to IC 5-11-5.5 on behalf of herself and the State of Indiana.

713. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

COUNT THIRTY-THREE
Indiana False Claims and Whistleblower Protection Act
Ind. Code § 5-11-5.5(b)(2)

714. Plaintiffs Arriazola and the State of Indiana reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

715. This Count is brought by Arriazola on behalf of the State of Indiana under the *qui tam* provisions of the Indiana False Claims and Whistleblower Act, IC 5-11-5.5 and pursuant to that Act seeks recovery of civil penalties, treble damages and the cost of the civil action.

716. The Indiana False Claims and Whistleblower Act, IC 5-11-5.5-2(b) (2005), specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the State for civil penalties and three times the amount of damages that the State sustains because of the act of that person, including:

(6) Makes or uses a false record or statement to avoid an obligation to pay or transmit property to the State; or

(8) Causes or induces another person to perform an act described above.

717. Defendants violated Indiana False Claims and Whistleblower Act, IC 5-11-5.5 by making, using or causing to be made or used false records or statements to support false claims submitted or caused to be submitted by Defendants and/or to conceal their actions and to avoid or decrease obligations to pay or transmit money to the State.

718. Defendants further violated Indiana False Claims and Whistleblower Act, IC 5-11-5.5 and knowingly and intentionally caused hundreds of thousands of false claims and/or records to be presented to the State of Indiana as well as made or used or caused to be made or used false records or statements to support such false claims and/or to avoid or decrease their obligation to pay or transmit money to the State from 1998 to the present by their violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best-Pricing Requirements, as described herein.

719. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Indiana in connection with Defendants' illegal practices.

720. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Indiana but for the illegal practices of Defendants described in this complaint.

721. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

722. Had the State of Indiana known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

723. As a result of Defendants' violations of IC 5-11-5.5, the State of Indiana has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

724. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to IC 5-11-5.5 on behalf of herself and the State of Indiana.

725. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

COUNT THIRTY-FOUR
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. § 46-438.3(A)

726. Plaintiffs Arriazola and the State of Louisiana reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

727. This Count is brought by Arriazola on behalf of the State of Louisiana under the *qui tam* provisions of Louisiana False Claims Act/Medical Assistance Programs Integrity Law 46 La. Rev. Stat. c.3 §437.1 *et seq.* and pursuant to the provisions of that law seek recovery of civil penalties, treble damages and the cost of the civil action.

728. The Louisiana False Claims Act/Medical Assistance Programs Integrity Law 46 La. Rev. Stat. c. §438.3 provides:

> (A) No person shall knowingly present or cause to be present a false or fraudulent claim;

729. In addition, La. Rev. Stat. Ann § 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducement, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing health care goods or services paid for in whole or in part by the Louisiana medical assistance programs.

730. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Louisiana.

731. Defendants violated La. Rev. Stat. Ann § 438.2(A) from at least 1998 to the present by engaging in the illegal practices described herein.

732. Defendants further violated La. Rev. Stat. c.3 §438.3(A) by presenting or causing to be presented false or fraudulent claims to be made to the State of Louisiana as well as through their violations of federal and Louisiana state laws including La. Rev. Stat. Ann. §438.2(A), the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

733. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Louisiana in connection with Amgen's illegal practices.

734. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Louisiana but for the illegal practices of Defendants described in this complaint.

735. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

736. Had the State of Louisiana known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

737. As a result of Defendants' violations of La. Rev. Stat. c. §438.3(A), the State of Florida has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

738. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to La. Rev. Stat. c.3 §439.1(A) on behalf of herself and the State of Louisiana.

739. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

COUNT THIRTY-FIVE
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. § 46-438.3(B)

740. Plaintiffs Arriazola and the State of Louisiana reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

741. This Count is brought by Arriazola on behalf of the State of Louisiana under the *qui tam* provisions of the Louisiana False Claims Act/Medical Assistance Programs Integrity Law 46 La. Rev. Stat. c.3 §437.1 *et seq.* and pursuant to the provisions of that law seek recovery of civil penalties, treble damages and the cost of the civil action.

742. The Louisiana False Claims Act/Medical Assistance Programs Integrity Law 46 La. Rev. Stat. c.3 §438.3 provides:

(B) No person shall knowingly engage in misrepresent to obtain, or attempt to obtain, payment from medical assistance program funds;

743. In addition, La. Rev. Stat. Ann § 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducement, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing health care goods or services paid for in whole or in part by the Louisiana medical assistance programs.

744. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Louisiana.

745. Defendants violated La. Rev. Stat. Ann § 438.2(B) from at least 1998 to the present by engaging in the illegal practices described herein.

746. Defendants further violated La. Rev. Stat. c.3 §438.3(B) by knowingly engaging in misrepresentation and made, used and caused to be made and used, false records and statement to obtain or attempt to obtain payment from or get false and fraudulent claims paid and approved by the State of Louisiana as well as through their violations of federal and Florida state laws including La. Rev. Stat. Ann. §438.2(A), the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

747. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Louisiana in connection with Amgen's illegal practices.

748. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Louisiana but for the illegal practices of Defendants described in this complaint.

749. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

750. Had the State of Louisiana known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

751. As a result of Defendants' violations of La. Rev. Stat. c. §438.3(A), the State of Louisiana has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

752. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to La. Rev. Stat. c.3 §439.1(A) on behalf of herself and the State of Louisiana.

753. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

COUNT THIRTY-SIX
Louisiana Medical Assistance Programs Integrity Law
46 La. Rev. Stat. § 46-438.3(C)

754. Plaintiffs Arriazola and the State of Louisiana reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

755. This Count is brought by Arriazola on behalf of the State of Louisiana under the *qui tam* provisions of the Louisiana False Claims Act/Medical Assistance Programs Integrity Law 46 La. Rev. Stat. c.3 §437.1 *et seq.* and pursuant to the provisions of that law seek recovery of civil penalties, treble damages and the cost of the civil action.

756. The Louisiana False Claims Act/Medical Assistance Programs Integrity Law 46 La. Rev. Stat. c. §438.3(C) provides:

> (C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

757. In addition, La. Rev. Stat. Ann § 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducement, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing health care goods or services paid for in whole or in part by the Louisiana medical assistance programs.

758. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Louisiana.

759. Defendants violated La. Rev. Stat. Ann § 438.2(A) from at least 1998 to the present by engaging in the illegal practices described herein.

760. Defendants further violated La. Rev. Stat. c.3 §438.3(C) by conspiring to defraud the State of Louisiana by getting false and fraudulent claims allowed and paid as well as through their violations of federal and Florida state laws including La. Rev. Stat. Ann. §438.2(A), the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

761. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Louisiana in connection with Amgen's illegal practices.

762. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been

submitted to the State of Louisiana but for the illegal practices of Defendants described in this complaint.

763. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

764. Had the State of Louisiana known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

765. As a result of Defendants' violations of La. Rev. Stat. c. §438.3(C), the State of Louisiana has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

766. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to La. Rev. Stat. c. §439.1(A) on behalf of herself and the State of Louisiana.

767. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

COUNT THIRTY-SEVEN
Louisiana Medical Assistance Programs Integrity Law
46 La. Rev. Stat. § 46-438.3(D)

768. Plaintiffs Arriazola and the State of Louisiana reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

769. This Count is brought by Arriazola on behalf of the State of Louisiana under the *qui tam* provisions of the Louisiana False Claims Act/Medical Assistance Programs

Integrity Law, La. Rev. Stat. § 46-437.1 *et seq.* and pursuant to the provisions of that law seek recovery of civil penalties, treble damages and the cost of the civil action.

The Louisiana False Claims Act/Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46-438.3(D) provides:

> (D) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

770. In addition, La. Rev. Stat. Ann. § 46-438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducement, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing health care goods or services paid for in whole or in part by the Louisiana medical assistance programs.

771. Defendant Amgen, acting in concert with its co-Defendants, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Louisiana.

772. Defendants violated La. Rev. Stat. Ann § 46-438.2(A) from at least 1998 to the present by engaging in the illegal practices described herein.

773. Defendants further violated La. Rev. Stat. § 46-438.3(D) by conspiring to defraud the State of Louisiana by getting false and fraudulent claims allowed and paid as well as through their violations of federal and Louisiana state laws including La. Rev. Stat. Ann. § 46-438.2(A), the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

774. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and

belief an express condition, of payment of claims submitted to the State of Louisiana in connection with Defendants' illegal practices.

775. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta, and its other drugs would not have been submitted to the State of Louisiana but for the illegal practices of Defendants described in this Third Amended Complaint .

776. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

777. Had the State of Louisiana known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

778. As a result of Defendants' violations of La. Rev. Stat. § 46-438.3(D), the State of Louisiana has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

779. Arriazola is a private person with direct and independent knowledge of the allegations in this Third Amended Complaint , who has brought this action pursuant to La. Rev. Stat. § 46-439.1(A) on behalf of herself and the State of Louisiana.

780. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

COUNT THIRTY-EIGHT
Louisiana Medical Assistance Programs Integrity Law
46 La. Rev. Stat. c.3 §438.2A(1)

781. Plaintiffs Arriazola and the State of Louisiana reallege and incorporate by

reference each and every of the foregoing paragraphs as if fully set forth herein.

782. This Count is brought by Arriazola on behalf of the State of Louisiana under the *qui tam* provisions of the Louisiana False Claims Act/Medical Assistance Programs Integrity Law 46 La. Rev. Stat. c.3 §437.1 *et seq.* and pursuant to the provisions of that law seek recovery of civil penalties, treble damages and the cost of the civil action.

783. Louisiana False Claims Act/Medical Assistance Programs Integrity Law 46 La. Rev. Stat. c.3 §438.2A(1) specifically provides that:

> No person shall solicit, receive, offer or pay any remuneration, including but not limited to kickbacks, bribes, rebates, or …payments, directly or indirectly, overtly or covertly, in cash or in kind, for the following….
>
> > In return for referring an individual to a health care provider…for the furnishing or arranging to furnish any good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs.

784. In addition, the Louisiana False Claims Act/Medical Assistance Programs Integrity Law, *supra,* §438.3 provides that:

> No person shall knowingly present or cause to be presented a false or fraudulent claim…shall knowingly engage in misrepresentation to obtain, or attempt to obtain payment from medical assistance program funds…shall conspire to defraud, or attempt to defraud, the medical assistance programs…

785. Furthermore, the Louisiana False Claims Act/Medical Assistance Programs Integrity Law, *supra*, §438.4 provides:

> No person shall knowingly make, use or cause to be made or used a false, fictitious, or misleading statement in any form used for the purpose of certifying or qualifying any person for eligibility…to receive any good, service, or supply under the medical assistance programs which that person is not eligible to receive.

786. Defendants, acting individually or in collusion, solicited, received, offered and/or paid remuneration, including but not limited to kickbacks, bribes, and gifts, directly or indirectly, overtly or covertly, in cash or in kind, in return for prescribing or arranging the prescribing of drugs which are paid for by the Louisiana Medicaid program, in violation of 46 La. Rev. Stat c.3 §438.2A(1).

787. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Louisiana in connection with Amgen's illegal practices.

788. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Louisiana but for the illegal practices of Defendants described in this complaint.

789. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

790. Had the State of Louisiana known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

791. As a result of Defendants' illegal practices and illegal practices described herein, the State of Louisiana has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

792. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to La. Rev. Stat. c. §439.1(A) on behalf of herself and the State of Louisiana.

793. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

COUNT THIRTY-NINE
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12, §5B(1)

794. Plaintiffs Arriazola and the Commonwealth of Massachusetts reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

795. This Count is brought by Arriazola on behalf of the Commonwealth of Massachusetts under the *qui tam* provisions of the Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 §5(A) *et seq.* and pursuant to the provisions of that law seek recovery of civil penalties, treble damages and the cost of the civil action.

796. The Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 §5(B)(1), provides in part, that any person who:

> Knowingly presents, or causes to be presented, a false or fraudulent claim for payment;...
>
> Shall liable to the Commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three (3) times the amount of damages, including consequential damages, that the Commonwealth or political subdivision sustains because of the act of that person.

797. In addition, Mass. Gen. Laws Ann. Chap. 118E §41 prohibits the solicitation, receipt or offering of any remuneration, including any brine or rebate,

directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid Program.

798. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the Commonwealth of Massachusetts.

799. Defendants violated Mass. Gen. Laws Ann. Chap. 118E §41 from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

800. Defendants further violated Mass. Gen. Laws Ann. Chap. 12 §5B from at least 1998 by presenting or causing to be presented to the Massachusetts Medicaid program false and fraudulent claims for payment and approval as well as through their violations of federal and Massachusetts laws including Mass. Gen. Laws Ann. Chap. 118E §41, the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

801. The claims caused to be submitted by Defendants knowingly failed to disclose the material violations of the state and federal laws cited herein, including the AKS and the companion law of the Commonwealth of Massachusetts cited herein.

802. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendants' illegal practices.

803. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the Commonwealth of Massachusetts but for the illegal practices of Defendants described in this complaint.

804. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

805. Had the Commonwealth of Massachusetts known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

806. As a result of Defendants' violations of Mass Gen. Laws. Ann. Chap. 12 §5B, the Commonwealth of Massachusetts has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

807. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Mass. Gen. Laws. Ann. Chap. 12 §5(c)(2) on behalf of herself and the Commonwealth of Massachusetts.

808. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

COUNT FORTY
Massachusetts False Claims Law
Mass. Gen. Laws Ch. 12, § 5B(2)

809. Plaintiffs Arriazola and the Commonwealth of Massachusetts reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

810. This Count is brought by Arriazola on behalf of the Commonwealth of Massachusetts under the *qui tam* provisions of the Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 §5(A) *et seq.* and pursuant to the provisions of that law

seek recovery of civil penalties, treble damages and the cost of the civil action.

811. The Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 §5(B)(2), provides in part, that any person who:

> Knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the Commonwealth or any political subdivision thereof;...
>
> Shall liable to the Commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three (3) times the amount of damages, including consequential damages, that the Commonwealth or political subdivision sustains because of the act of that person.

812. In addition, Mass. Gen. Laws Ann. Chap. 118E §41 prohibits the solicitation, receipt or offering of any remuneration, including any brine or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid Program.

813. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the Commonwealth of Massachusetts.

814. Defendants violated Mass. Gen. Laws Ann. Chap. 118E §41 from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

815. Defendants further violated Mass. Gen. Laws Ann. Chap. 12 §5B by making or using or causing to be made or used with the requisite intent false records and statements to obtain payment or approval of claims by the Commonwealth of Massachusetts as well as through their violations of federal and Massachusetts laws including Mass. Gen. Laws Ann. Chap. 118E §41, the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

816. The claims caused to be submitted by Defendants knowingly failed to disclose the material violations of the state and federal laws cited herein, including the AKS and the companion law of the Commonwealth of Massachusetts cited herein.

817. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendants' illegal practices.

818. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the Commonwealth of Massachusetts but for the illegal practices of Defendants described in this complaint.

819. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

820. Had the Commonwealth of Massachusetts known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

821. As a result of Defendants' violations of Mass Gen. Laws. Ann. Chap. 12 §5B, the Commonwealth of Massachusetts has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

822. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Mass. Gen. Laws. Ann. Chap. 12 §5(c)(2) on behalf of herself and the Commonwealth of Massachusetts.

823. This Court is requested to accept pendant jurisdiction of this related state

claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

COUNT FORTY-ONE
Massachusetts False Claims Law
Mass. Gen. Laws Ch. 12 §5B(3)

824. Plaintiffs Arriazola and the Commonwealth of Massachusetts reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

825. This Count is brought by Arriazola on behalf of the Commonwealth of Massachusetts under the *qui tam* provisions of the Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 §5(A) *et seq.* and pursuant to the provisions of that law seek recovery of civil penalties, treble damages and the cost of the civil action.

826. The Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 §5(B)(3), provides in part, that any person who:

> Conspires to defraud the Commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;...
>
> Shall liable to the Commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three (3) times the amount of damages, including consequential damages, that the Commonwealth or political subdivision sustains because of the act of that person.

827. In addition, Mass. Gen. Laws Ann. Chap. 118E §41 prohibits the solicitation, receipt or offering of any remuneration, including any brine or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid Program.

828. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the Commonwealth of Massachusetts.

829. Defendants violated Mass. Gen. Laws Ann. Chap. 118E §41 from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

830. Defendants further violated Mass. Gen. Laws Ann. Chap. 12 §5B by making or using or causing to be made or used with the requisite intent false records and statements to obtain payment or approval of claims by the Commonwealth of Massachusetts as well as through their violations of federal and Massachusetts laws including Mass. Gen. Laws Ann. Chap. 118E §41, the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

831. The claims caused to be submitted by Defendants knowingly failed to disclose the material violations of the state and federal laws cited herein, including the AKS and the companion law of the Commonwealth of Massachusetts cited herein.

832. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendants' illegal practices.

833. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the Commonwealth of Massachusetts but for the illegal practices of Defendants described in this complaint.

834. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

835. Had the Commonwealth of Massachusetts known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

836. As a result of Defendants' violations of Mass Gen. Laws. Ann. Chap. 12 §5B, the Commonwealth of Massachusetts has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

837. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Mass. Gen. Laws. Ann. Chap. 12 §5(c)(2) on behalf of herself and the Commonwealth of Massachusetts.

838. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

COUNT FORTY-TWO
Massachusetts False Claims Law
Mass. Gen. Laws Ch. 12 §5B(8)

839. Plaintiffs Arriazola and the Commonwealth of Massachusetts reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

840. This Count is brought by Arriazola on behalf of the Commonwealth of Massachusetts under the *qui tam* provisions of the Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 §5(A) *et seq.* and pursuant to the provisions of that law seek recovery of civil penalties, treble damages and the cost of the civil action.

841. The Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12

§5(B)(8), provides in part, that any person who:

> Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the Commonwealth;
>
> Shall liable to the Commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three (3) times the amount of damages, including consequential damages, that the Commonwealth or political subdivision sustains because of the act of that person.

842. In addition, Mass. Gen. Laws Ann. Chap. 118E §41 prohibits the solicitation, receipt or offering of any remuneration, including any brine or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid Program.

843. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the Commonwealth of Massachusetts.

844. Defendants violated Mass. Gen. Laws Ann. Chap. 118E §41 from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

845. Defendants further violated Mass. Gen. Laws Ann. Chap. 12 §5B by making or using or causing to be made or used with the requisite intent false records and statements to obtain payment or approval of claims by the Commonwealth of Massachusetts as well as through their violations of federal and Massachusetts laws including Mass. Gen. Laws Ann. Chap. 118E §41, the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

846. The claims caused to be submitted by Defendants knowingly failed to disclose the material violations of the state and federal laws cited herein, including the AKS and the companion law of the Commonwealth of Massachusetts cited herein.

847. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendants' illegal practices.

848. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the Commonwealth of Massachusetts but for the illegal practices of Defendants described in this complaint.

849. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

850. Had the Commonwealth of Massachusetts known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

851. As a result of Defendants' violations of Mass Gen. Laws. Ann. Chap. 12 §5B, the Commonwealth of Massachusetts has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

852. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Mass. Gen. Laws. Ann. Chap. 12 §5(c)(2) on behalf of herself and the Commonwealth of Massachusetts.

853. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

COUNT FORTY-THREE
Michigan Medicaid False Claims Act
Mich. Comp. Laws Ann. § 400.601 *et seq.*

854. Plaintiffs Arriazola and the State of Michigan reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

855. This Count is brought by Arriazola on behalf of the State of Michigan under the *qui tam* provisions of the Michigan Medicaid False Claims Act, M.C.L.A. 400.601 *et seq.*, and pursuant to the provisions of that law Plaintiffs seek recovery of civil penalties, treble damages and the cost of the civil action.

856. Michigan Medicaid False Claims Act, M.C.L.A. 400.603 provides that:

(1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits.

(2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit.

(3) A person, who having knowledge of the occurrence of an event affecting his initial or continued right to receive a Medicaid benefit or the initial or continued right of any other person on whose behalf he has applied for or is receiving a benefit, shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled.

857. Michigan Medicaid False Claims Act, M.C.L.A. 400.606 provides that

(1) A person shall not enter into an agreement, combination, or conspiracy to defraud the State by obtaining or aiding another to obtain the payment or allowance of a false claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, being sections 400.1 to 400.121 of the Michigan Compiled Laws.

858. Michigan Medicaid False Claims Act, M.C.L.A. 400.607 provides that

(1) A person shall not make or present or cause to be made or presented to an employee or officer of this State a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, being sections 400.1 to 400.121

of the Michigan Compiled Laws, upon or against the State, knowing the claim to be false.

(2) A person shall not make or present or cause to be made or presented a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, which he or she knows falsely represents that the goods or services for which the claim is made were medically necessary in accordance with professionally accepted standards. Each claim violating this subsection shall constitute a separate offense. A health facility or agency shall not be liable under this subsection unless the health facility or agency, pursuant to a conspiracy, combination, or collusion with a physician or other provider, falsely represents the medical necessity of the particular goods or services for which the claim was made.

859. Michigan Medicaid False Claims Act, M.C.L.A. 400.604 provides that

A person who solicits, offers, or receives a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made in whole or in part pursuant to a program established under Act No. 280 of the Public Acts of 1939, as amended, who makes or receives the payment, or who receives a rebate of a fee or charge for referring an individual to another person for the furnishing of the goods and services is guilty of a felony, punishable by imprisonment for not more than 4 years, or by a fine of not more than $30,000.00, or both.

860. Michigan Medicaid False Claims Act, M.C.L.A. 400.612 provides that

(1) A person who receives a benefit which the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact shall forfeit and pay to the State a civil penalty equal to the full amount received plus triple the amount of damages suffered by the State as a result of the conduct by the person.

861. Defendants violated the above referenced provisions of the Michigan Medicaid False Claims Act from at least 1998 to the present by engaging in the fraudulent and illegal practices described herein.

862. Defendants further violated MCLA 400.601 *et seq.* by the conduct alleged in this Complaint, including by presenting false claims or causing to be presented false claims to the State of Michigan; making or using or causing to be made or used false records or statements to get false claims paid; by conspiring to defraud the State by

obtaining or aiding another to obtain the payment or allowance of a false claim; by making or using or causing to be made or used, with the requisite intent, false records and statements to obtain payment or approval of claims by the State; and by making or using false records or statement, or causing to be made such false records or statements in order to avoid or decrease their obligation to pay monies to the State of Michigan.

863. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of Michigan but for the illegal practices of Defendants described in this complaint.

864. Defendants further violated 400.601 *et seq.* through their violations of federal and state laws including MCLA 400.604, the Anti-Kickback Act, and Best Pricing Requirements, as described herein.

865. The claims caused to be submitted by Defendants knowingly failed to disclose the material violations of the state and federal laws cited herein, including the AKS and the companion law of the State of Michigan cited herein.

866. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Michigan in connection with Defendants' illegal practices.

867. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

868. Had the State of Michigan known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in

connection with Defendants' fraudulent and illegal practices.

869. As a result of Defendants' violations of M.C.L.A. 400.601 *et seq.*, the State of Michigan has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

870. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to M.C.L.A. 400.610a on behalf of herself and the State of Michigan.

871. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

COUNT FORTY-FOUR
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §§ 167:61-b *et seq.*

872. Plaintiffs Arriazola and the State of New Hampshire reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

873. This is a qui tam action brought by Arriazola on behalf of the State of New Hampshire to recover treble damages, civil penalties and the cost of the civil action under the New Hampshire False Claims Act, N.H. RSA §§167:61-b, *et seq.*

874. The New Hampshire False Claims Act, N.H. RSA §§167:61-b I *et seq.*, sustains because of the act of that person, who:

(a) Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval.

875. Amgen, at all times relevant to this action, sold and continues to sell

pharmaceuticals in the State of New Hampshire.

876. Defendants further violated N.R.S. §167:61-b I (a) by presenting or causing to be presented false and/or fraudulent claims for payment and approval and such claims failed to disclose the material violations of the law as well as through their violations of federal and New Hampshire state laws including the Anti-Kickback Act and Best Pricing Requirements, as described herein.

877. The claims caused to be submitted by Defendants knowingly failed to disclose the material violations of the state and federal laws cited herein, including the AKS and the companion law of the State of New Hampshire cited herein.

878. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of New Hampshire in connection with Defendants' illegal practices.

879. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of New Hampshire but for the illegal practices of Defendants described in this complaint.

880. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

881. Had the State of New Hampshire known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

882. As a result of Defendants' violations of N.H. RSA §167:61-b *et seq*, the

State of New Hampshire has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

883. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to N.H. RSA § 167:61-c II on behalf of herself and the State of New Hampshire.

884. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

COUNT FORTY-FIVE
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §§ 167:61-b *et seq.*

885. Plaintiffs Arriazola and the State of New Hampshire reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

886. This is a qui tam action brought by Arriazola on behalf of the State of New Hampshire to recover treble damages, civil penalties and the cost of the civil action under the New Hampshire False Claims Act, N.H. RSA §§167:61-b, *et seq.*

887. The New Hampshire False Claims Act, N.H. RSA §§167:61-b I *et seq.*, provides that any person shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three (3) times the amount of damages that the State sustains because of the act of that person, who:

> (b) Makes, uses or causes to be made or used a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the State knowing such record or statement is false;

888. Amgen, at all times relevant to this action, sold and continues to sell

pharmaceuticals in the State of New Hampshire.

889. Defendants further violated N.R.S. §167:61-b I(b) by knowingly making or using or causing to be made or used a false record or statement to get false or fraudulent claims made to the New Hampshire Medicaid program paid or approved with the requisite knowledge that the claims were false or fraudulent and with the requisite knowledge that such claims failed to disclose the material violations of the law as well as through their violations of federal and New Hampshire state laws including the Anti-Kickback Act and Best Pricing Requirements, as described herein.

890. The claims caused to be submitted by Defendants knowingly failed to disclose the material violations of the state and federal laws cited herein, including the AKS and the companion law of the State of New Hampshire cited herein.

891. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of New Hampshire in connection with Defendants' illegal practices.

892. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of New Hampshire but for the illegal practices of Defendants described in this complaint.

893. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

894. Had the State of New Hampshire known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in

connection with Defendants' fraudulent and illegal practices.

895. As a result of Defendants' violations of N.H. RSA §167:61-b *et seq*, the State of New Hampshire has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

896. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to N.H. RSA § 167:61-c II on behalf of herself and the State of New Hampshire.

897. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

COUNT FORTY-SIX
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §§ 167:61-b *et seq.*

898. Plaintiffs Arriazola and the State of New Hampshire reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

899. This is a qui tam action brought by Arriazola on behalf of the State of New Hampshire to recover treble damages, civil penalties and the cost of the civil action under the New Hampshire False Claims Act, N.H. RSA §§167:61-b, *et seq.*

900. The New Hampshire False Claims Act, N.H. RSA §§167:61-b I *et seq.*, provides that any person shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three (3) times the amount of damages that the State sustains because of the act of that person, who:

(c) Conspires to defraud the State by getting acclaim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent;

901. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of New Hampshire.

902. Defendants further violated N.R.S. §167:61-b I (c) by conspiring to defraud the State by getting claims allowed or paid under the Medicaid program knowing that such claims were false or fraudulent as well as through their violations of federal and New Hampshire state laws including the Anti-Kickback Act and Best Pricing Requirements, as described herein.

903. The claims caused to be submitted by Defendants knowingly failed to disclose the material violations of the state and federal laws cited herein, including the AKS and the companion law of the State of New Hampshire cited herein.

904. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of New Hampshire in connection with Defendants' illegal practices.

905. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of New Hampshire but for the illegal practices of Defendants described in this complaint.

906. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

907. Had the State of New Hampshire known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in

connection with Defendants' fraudulent and illegal practices.

908. As a result of Defendants' violations of N.H. RSA §167:61-b *et seq*, the State of New Hampshire has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

909. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to N.H. RSA § 167:61-c II on behalf of herself and the State of New Hampshire.

910. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

COUNT FORTY-SEVEN
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §§ 167:61-b *et seq.*

911. Plaintiffs Arriazola and the State of New Hampshire reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

912. This is a qui tam action brought by Arriazola on behalf of the State of New Hampshire to recover treble damages, civil penalties and the cost of the civil action under the New Hampshire False Claims Act, N.H. RSA §§167:61-b, *et seq.*

913. The New Hampshire False Claims Act, N.H. RSA §§167:61-b I *et seq.*, provides that any person shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three (3) times the amount of damages that the State sustains because of the act of that person, who:

(e) Makes, uses, or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State, relative to the Medicaid program, knowing that such record or statement is false.

914. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of New Hampshire.

915. Defendants further violated N.H. R.S.A. §167:61-b I (e) by making, using or causing to be made or used false records or statements to conceal, avoid or decrease an obligation to pay or transmit money or property to the State, with the requisite knowledge concerning the falsity of such records or statements as well as through their violations of federal and New Hampshire state laws including the Anti-Kickback Act and Best Pricing Requirements, as described herein.

916. The claims caused to be submitted by Defendants knowingly failed to disclose the material violations of the state and federal laws cited herein, including the AKS and the companion law of the State of New Hampshire cited herein.

917. Compliance with the applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of New Hampshire in connection with Defendants' illegal practices.

918. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of New Hampshire but for the illegal practices of Defendants described in this complaint.

919. At all times relevant to the Complaint, Defendants acted with the requisite knowledge in violating the state and federal statutes cited herein.

920. Had the State of New Hampshire known that Defendants were violating the state and federal laws cited herein, it would not have paid the claims submitted to it in connection with Defendants' fraudulent and illegal practices.

921. As a result of Defendants' violations of N.H. RSA §167:61-b *et seq*, the State of New Hampshire has sustained damages in an amount far in excess of millions of dollars exclusive of interest.

922. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to N.H. RSA § 167:61-c II on behalf of herself and the State of New Hampshire.

923. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

COUNT FORTY-EIGHT
New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-1 *et seq.*

924. Plaintiffs Arriazola and the State of New Mexico reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

925. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act (2004) N.M. Stat. Ann. §27-14-1 *et seq.*

926. Section 4 of the New Mexico Medicaid False Claims Act provides that "[a] person commits an unlawful act if the person:

A. Presents, or causes to be presented, to the State a claim for payment under the Medicaid program knowing that such claim is false or fraudulent;

B. Presents, or causes to be presented, to the State a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or

payment is not authorized or is not eligible for a benefit under the Medicaid program;

C. Makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the State knowing such record or statement is false;

D. Conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent;

E. Makes, uses or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State, relative to the Medicaid program, knowing that such record or statement is false;

F. Knowingly or intentionally applies for and receives a benefit for payment on behalf of another person under the Medicaid program and converts any part of the benefit or payment to a use other than for the benefit of the person on whose behalf it was received;

G. Knowingly or intentionally makes a false statement or misrepresentation of material fact concerning the conditions or operation of a health care facility in order that the facility may qualify for certification or recertification required by the Medicaid program; or

H. Knowingly or intentionally makes a claim under the Medicaid program for a service or product that is substantially inadequate or inappropriate when compared to generally recognized standards within the particular discipline or health care industry.

927. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of New Mexico. Amgen, at all times relevant to this action, has operated and continues to operate pharmaceutical distribution facilities in the State of New Mexico.

928. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of New Mexico but for the illegal practices of Defendants described in this complaint.

929. By virtue of this illegal conduct and the other misconduct alleged herein, including the exchange of kickbacks and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions, and used false or fraudulent records to accomplish this purpose.

930. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

931. By reason of these improper payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT FORTY-NINE
New Mexico Anti-Kickback Statute
N.M. Stat.§§ 30-41-1 *et seq.*

932. Plaintiffs Arriazola and the State of New Mexico reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

933. Through an organized system of "speaker bureaus," consultant payments, honoraria, advisory board memberships, and other titles disguising payments intended to influence "scientific" findings and administrative decisions that resulted in widespread prescription of and governmental reimbursement for Amgen's drugs, the Defendants established a system of kickbacks. The kickbacks took the form of honoraria (including the unrestricted grants described *supra*, and other benefits.

934. These kickbacks had the effect of greatly increasing the amount of prescriptions of Amgen's drugs and consequently the amount of state and federal governmental money spent to cover the drug's costs. The payment of these kickbacks

represents the inducement of payments through a pattern of fraudulent conduct, and constitutes a false claim within the meaning of N.M. Laws 2007, Ch. 40, §3 (48th Leg. 1st Sess.).

COUNT FIFTY
New Mexico Fraud Against Taxpayers Act
N.M. Stat. § 44-9-1 *et seq.*

935. Plaintiffs Arriazola and the State of New Mexico reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

936. This is a qui tam action brought by Arriazola on behalf of the State of New Mexico to recover treble damages, civil penalties and the cost of the civil action under the New Mexico Fraud Against Taxpayers Act.

937. Section 3 (A) of the new Mexico Fraud Against Taxpayers Act provides that [a] person shall not:

> (1) Knowingly present, or cause to be presented, to an employee, officer or agent of the State or to a contractor, grantee or other recipient of State funds a false or fraudulent claim for payment or approval;
>
> (2) Knowingly make or use, or cause to be made or used, a false record or statement to obtain approval or payment on a false or fraudulent claim;
>
> (3) Conspire to defraud the State by obtaining approval or payment on a false claim;
>
> (7) Knowingly make or use, or cause to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State; or
>
> (8) As a beneficiary of an inadvertent submission of a false claim and having subsequently discovered the falsity of the claim, fail to disclose the false claim to the State agency within a reasonable time after discovery.

938. Pursuant to Section 3 (B) of the New Mexico Fraud Against Taxpayers Act, proof of specific intent is not required for a violation of subsection A of Section 3.

939. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of New Mexico and has operated and continues to operate pharmaceutical distribution facilities in the State of New Mexico.

940. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of New Mexico but for the illegal practices of Defendants described in this complaint.

941. By virtue of this illegal conduct and the other misconduct alleged herein, including the exchange of undisclosed kickbacks, causing the submissions of non-reimbursable claims for prescription drugs described above and using or causing to be used false or fraudulent records to accomplish this purpose, as well as the use of false records to conceal avoid or decrease an obligation to transmit money to the State, Defendants violated Section 3 (A) of the new Mexico Fraud Against Taxpayers Act with the requisite intent.

942. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

943. By reason of these improper payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

944. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Section 5 of the New Mexico Fraud Against Taxpayers Act on behalf of herself and the State of New Mexico.

945. This Court is requested to accept pendant jurisdiction of this related state

claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

COUNT FIFTY-ONE
New York False Claims Act
N.Y. State Fin. §§ 187 et. seq.

946. Plaintiffs Arriazola and the State of New York reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

947. This is a qui tam action brought by Arriazola on behalf of the State of New York to recover treble damages, civil penalties and the cost of the civil action under the *qui tam* provisions of the New York False Claims Act, New York Finance Law, Article XIII, §187 *et seq.*

948. McKinney's State Finance Law §189(1)(a) provides liability for any person who-

> Knowingly presents, or causes to be presented, to any employee, officer or agent of the State or local government, a false or fraudulent claim for payment or approval.

949. Pursuant to McKinney's State Finance Law §189, a person who violates this provision may be held liable for a civil penalty of not less than $6,000 and not more than $12,000 for each false claim presented or caused to be presented to the State of New York plus three times the amount of damages the State of New York sustains because of the actions of that person, and all costs incurred in bringing the instant action.

950. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of New York.

951. By virtue of the above-described acts, among others, Defendant Amgen and the other Defendants knowingly caused to be presented false or fraudulent claims for

payment or approval, and possibly continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of New York, for Aranesp, Neulasta and other drugs.

952. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of New York but for the illegal practices of Defendants described in this complaint.

953. Defendants further violated McKinney's State Finance Law §189 and knowingly caused hundreds of thousands of false claims to be submitted to the State of New York from at least 1998 to the present by their violation of federal and state law, including the Anti-kickback Statute, the Stark Act and Best Pricing Requirements, as described herein.

954. For example, claims for reimbursement for off-label prescriptions of Amgen's drugs Aranesp, Enbrel, Neulasta and its other drugs would not have been submitted to the State of New York but for the illegal practices of Defendants described in this complaint.

955. Compliance with applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and belief also an express condition of payment of claims submitted to the State of New York in connection with Defendants' fraudulent and illegal practices.

956. The amounts of the false or fraudulent claims to the State of New York were material.

957. Plaintiff State of New York, being unaware of the falsity of the claims

and/or statements made by the Defendants, and in reliance on the accuracy thereof paid and may continue to pay for Defendants' improperly prescribed drugs.

958. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

959. By reason of these improper payments, the New York Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

960. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to McKinney's State Finance Law §189 on behalf of herself and the State of New York.

961. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

COUNT FIFTY-TWO
New York False Claims Act
N.Y. State Fin. §§ 187 et. seq.

962. Plaintiffs Arriazola and the State of New York reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

963. This is a qui tam action brought by Arriazola on behalf of the State of New York to recover treble damages, civil penalties and the cost of the civil action under the *qui tam* provisions of the New York False Claims Act, New York Finance Law, Article XIII, §§187 *et seq.*

964. McKinney's State Finance Law §189(1)(b) provides liability for any person who-

> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State or local government.

965. Pursuant to McKinney's State Finance Law §189, a person who violates this provision may be held liable for a civil penalty of not less than $6,000 and not more than $12,000 for each false claim presented or caused to be presented to the State of New York plus three times the amount of damages the State of New York sustains because of the actions of that person, and all costs incurred in bringing the instant action.

966. At all times relevant and material to this Complaint, Defendants have induced a misallocation of New York's funds through a pattern of fraudulent conduct, including making false statements or records and/or causing false records or statements to be made to get false claims paid as alleged herein.

967. Defendants intentionally concealed their schemes to market their drugs in New York and throughout the United States for the purpose of, and with the effect of, unlawfully increasing purchases of Amgen prescription drugs by New York's Medicaid Program and the Medicare Part D Program that would not have funded but for Defendants' unlawful conduct detailed herein.

968. By the conduct alleged in this Third amended complaint, Defendants have knowingly and foreseeably caused false drug reimbursement claims for Amgen products Aranesp, Neulasta and other drugs to be paid or approved that Defendants knew to be ineligible for reimbursement and the cost of which would be borne by New York by and through, *inter alia,* New York's Medicaid Program, by making or using, or causing to be made or used false records and/or statements.

969. Defendants further violated McKinney's State Finance Law §189 and

knowingly caused hundreds of thousands of false claims to be submitted to the State of New York from at least 1998 to the present by their violation of federal and state law, including the Anti-kickback Statute, the Stark Act and Best Pricing Requirements, as described herein.

970. Compliance with applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and belief also an express condition of payment of claims submitted to the State of New York in connection with Defendants' fraudulent and illegal practices.

971. Defendants' conduct includes its deceptive and illegal scheme to expand off-label use of Aranesp, Neulasta and other drugs by, *inter alia*, 1) marketing the spread for Aranesp, Neulasta and other drugs, 2) marketing Aranesp, Neulasta and other drugs in a misleading and/or disingenuous way for off-label uses and populations to physicians in the long term care and primary care markets and 2) orchestrating kickback schemes. As a result, the State of New York has allowed, paid or otherwise funded claims submitted by pharmacies, physicians and other providers for reimbursement of Aranesp, Neulasta and other drugs, resulting in great financial loss to the State.

972. Defendants' conduct constitutes the intentional and knowing violation of the New York False Claims Act and other laws.

973. The records and claims made or used, or caused or made to be used by Defendants were intended to get false reimbursement claims for Aranesp, Neulasta and other drugs paid and allowed. The claims Defendants caused to be paid themselves were false as that term is defined by New York law.

974. The New York False Claims Act has been repeatedly violated by

Defendants through the fact that their conduct of making or using or causing to be made or used false records or statements, were intended to and did resulted in false claims submitted and paid, pursuant to underlying financial transactions that violated the Anti-Kickback Statute. Such claims were submitted to the State of New York containing the false certification of compliance with this among other federal statutes.

975. The submission and payment of these falsely certified claims was the intended and foreseeable result of Defendants' conduct.

976. By virtue of the above-described acts, among others, Defendants knowingly caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State, and possibly continues to make or use false records or statements to get false or fraudulent claims paid or approved, directly or indirectly, to officers, employees, or agents of the State of New York, for Aranesp, Neulasta and other drugs.

977. The amounts of the false or fraudulent claims caused to be paid by New York finding because of the records or statements made or used or caused to be made or used by Defendants were material.

978. Plaintiff State of New York, being unaware of the falsity of records or statements made or used, or caused to be made or used, by Defendants, and in reliance on the accuracy thereof paid and may continue to pay for Aranesp, Neulasta and other drugs. All unlawful conduct described above began before and may have continued after Plaintiff-Relator Arriazola's employment.

979. The State of New York *ex rel.* Plaintiff-Relator is entitled to multiple damages under the New York False Claims Act, to be determined at trial, plus a civil

penalty of $6,000 to $12,000 for each false record or statement made or used or caused to be made or used by Defendants to get false claims submitted to the State paid or allowed.

980. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to McKinney's State Finance Law §189 on behalf of herself and the State of New York.

981. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

COUNT FIFTY-THREE
New York False Claims Act
N.Y. State Fin. §§ 187 et. seq.

982. Plaintiffs Arriazola and the State of New York reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

983. This is a qui tam action brought by Arriazola on behalf of the State of New York to recover treble damages, civil penalties and the cost of the civil action under the *qui tam* provisions of the New York False Claims Act, New York Finance Law, Article XIII, §§187 *et seq.*

984. McKinney's State Finance Law §189(1)(c) provides liability for any person who-

> Conspires to defraud the State or a local government by getting a false or fraudulent claim allowed or paid;

985. Pursuant to McKinney's State Finance Law §189, a person who violates this provision may be held liable for a civil penalty of not less than $6,000 and not more than $12,000 for each false claim presented or caused to be presented to the State of New York plus three times the amount of damages the State of New York sustains because of

the actions of that person, and all costs incurred in bringing the instant action.

986. At all times relevant and material to this Complaint, Defendants have induced a misallocation of New York's funds through a pattern of fraudulent conduct, including conspiring with one another and others by getting false claims paid or allowed by the State of New York Medicaid program.

987. By entering into illegal kickback agreements as detailed herein, Defendants engaged in unlawful conspiracies as alleged herein to defraud the State of New York causing the submission of false claims for Aranesp, Neulasta and other drugs. At all times relevant to the complaint, Defendants and their co-conspirators knowingly violated McKinney's State Finance Law §189 and knowingly caused hundreds of thousands of false claims to be submitted to the State of New York from at least 1998 to the present by their violation of federal and state law, including the Anti-kickback Statute, the Stark Act and Best Pricing Requirements, as described herein.

988. Compliance with applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and belief also an express condition of payment of claims submitted to the State of New York in connection with Defendants' fraudulent and illegal practices.

989. As a result of the claims for reimbursement Defendants caused to be submitted to New York's Medicaid Program and Medicare Part D pursuant to the Defendants' conspiracies, those claims containing the false certification of compliance with the Anti-Kickback Statute and other laws as a condition of payment, New York regularly made payments to pharmacies and other providers to reimburse for the cost of Aranesp, Neulasta and other drugs.

990. The amounts of the false or fraudulent claims to the State of New York were material.

991. Plaintiff State of New York, being unaware of the falsity of the claims and/or statements caused to be made Defendant Amgen's kickback conspiracies, and in reliance on the accuracy thereof paid and may continue to pay for Aranesp, Neulasta and other drugs. All unlawful conduct described above began before and may have continued after Plaintiff-Relator Arriazola's employment.

992. The State of The State of New York *ex rel.* Plaintiff-Relator is entitled to multiple damages under the New York False Claims Act, to be determined at trial, plus a civil penalty of $6,000 to $12,000 for each ineligible claim submitted to New York's Medicaid Program for payment pursuant to Defendants' unlawful conspiracies.

993. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to McKinney's State Finance Law §189 on behalf of herself and the State of New York.

994. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

COUNT FIFTY-FOUR
New York False Claims Act
N.Y. State Fin. §§ 187 et. seq.

995. Plaintiffs Arriazola and the State of New York reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

996. This is a qui tam action brought by Arriazola on behalf of the State of New York to recover treble damages, civil penalties and the cost of the civil action under

the *qui tam* provisions of the New York False Claims Act, New York Finance Law, Article XIII, §§187 *et seq.*

997. McKinney's State Finance Law §189(1)(b) provides liability for any person who-

> Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State or a local government;

998. Pursuant to McKinney's State Finance Law §189, a person who violates this provision may be held liable for a civil penalty of not less than $6,000 and not more than $12,000 for each false claim presented or caused to be presented to the State of New York plus three times the amount of damages the State of New York sustains because of the actions of that person, and all costs incurred in bringing the instant action.

999. At all times relevant and material to this Complaint, by the conduct alleged herein, Defendants have induced a misallocation of New York's funds through a pattern of fraudulent conduct, making or using or causing to be made or used false records to conceal, avoid, or decrease an obligations to pay or transmit money or property to the State or a local government.

1000. Defendants intentionally concealed their illegal practices engaged in throughout New York and the United States for the purpose of, and with the effect of, unlawfully decreasing or avoiding their obligations to pay monies to the State of New York as well as to increase purchases of Amgen prescription drugs by New York's Medicaid Program and the Medicare Part D Program that would not have funded but for Defendants' unlawful conduct detailed herein.

1001. Defendants' conduct includes its deceptive and illegal scheme to expand

off-label use of Aranesp, Neulasta and other drugs by, *inter alia*, 1) marketing the spread for Aranesp, Neulasta and other drugs, 2) marketing Aranesp, Neulasta and other drugs in a misleading and/or disingenuous way for off-label uses and populations to physicians in the long term care and primary care markets and 2) orchestrating a kickback scheme involving the payment of rebates to private customers and concealing those rebates from the State of New York with the purpose of avoiding or decreasing their obligation to pay moneys to the State. As a result, the State of New York has suffered great financial loss to the State.

1002. Defendants further violated McKinney's State Finance Law §189 and knowingly caused hundreds of thousands of false claims to be submitted to the State of New York from at least 1998 to the present by their violation of federal and state law, including the Anti-kickback Statute, the Stark Act and Best Pricing Requirements, as described herein.

1003. Compliance with applicable Medicare, Medicaid and various other federal and state laws cited herein was an implied condition, and upon information and belief also an express condition of payment of claims submitted to the State of New York in connection with Defendants' fraudulent and illegal practices.

1004. Defendants' conduct constitutes the intentional violation of the New York False Claims Act and other laws.

1005. The records and claims made or used, or caused or made to be used by Defendants were intended to get false reimbursement claims for Aranesp, Neulasta and other drugs paid and allowed. The claims Defendants caused to be paid themselves were false as that term is defined by New York law.

1006. The New York False Claims Act has been repeatedly violated by Defendants through the fact that their conduct of making or using or causing to be made or used false records or statements, were intended to and did resulted in false claims submitted and paid, pursuant to underlying financial transactions that violated the Anti-Kickback Statute. Such claims were submitted to the State of New York containing the false certification of compliance with this among other federal statutes.

1007. The submission and payment of these falsely certified claims was the intended and foreseeable result of Defendants' conduct.

1008. By virtue of the above-described acts, among others, Defendants knowingly caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State, and possibly continues to make or use false records or statements to get false or fraudulent claims paid or approved, directly or indirectly, to officers, employees, or agents of the State of New York, for Aranesp, Neulasta and other drugs.

1009. The amounts of the false or fraudulent claims caused to be paid by New York finding because of the records or statements made or used or caused to be made or used by Defendants were material.

1010. Plaintiff State of New York, being unaware of the falsity of records or statements made or used, or caused to be made or used, by Defendants, and in reliance on the accuracy thereof paid and may continue to pay for Aranesp, Neulasta and other drugs. All unlawful conduct described above began before and may have continued after Plaintiff-Relator Arriazola's employment.

1011. The State of New York *ex rel.* Plaintiff-Relator is entitled to multiple

damages under the New York False Claims Act, to be determined at trial, plus a civil penalty of $6,000 to $12,000 for each false record or statement made or used or caused to be made or used by Defendants to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State or a local government.

1012. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to McKinney's State Finance Law §189 on behalf of herself and the State of New York.

1013. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

COUNT FIFTY-FIVE
Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(A)

1014. Plaintiffs Arriazola and the State of Tennessee reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1015. This is a qui tam action brought by Arriazola on behalf of the State of Tennessee to recover treble damages, civil penalties and the cost of the civil action under the *qui tam* provisions of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 *et seq.*

1016. Tenn. Code Ann. §§71-5-182 (a)(1)(A) provides liability for any person who-

> Presents or causes to be presented to the State, a claim for payment under the Medicaid Program knowing such claim is false or fraudulent;

1017. Pursuant to Tennessee's Medicaid False Claims Act, a person who violates this provision Tenn. Code Ann. §§71-5-181 *et seq.* is liable to the State for a civil

penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the State sustains because of the act of that person.

1018. Defendants violated Tenn. Code Ann. §71-5-182(a)(1) and knowingly caused hundreds of thousands of claims they knew to be false to be made, used and presented to the State of Tennessee from at least 1998 to the present by its violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best Pricing Requirements, as described herein. The claims caused to be submitted failed to disclose the material violations of the AKS and other federal and state laws, in violation of Tenn. Code Ann. §71-5-182(a)(1)(A).

1019. At all times relevant to this Complaint, Defendants acted with the requisite scienter in violating the federal and state law cited herein.

1020. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by healthcare providers in connection therewith.

1021. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Tennessee in connection with Defendants' fraudulent and illegal practices.

1022. Had the State of Tennessee known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers in connection with Defendants' fraudulent and illegal practices.

1023. As a result of Defendants' violations of Tenn. Code Ann. §71-5-182(a)(1)

, the State of Tennessee has been damages in an amount far in excess of millions of dollars exclusive on interest.

1024. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Tenn Code Ann. §71-5-183(a)(1) on behalf of herself and the State of Tennessee.

1025. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

COUNT FIFTY-SIX
Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(B)

1026. Plaintiffs Arriazola and the State of Tennessee reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1027. This is a qui tam action brought by Arriazola on behalf of the State of Tennessee to recover treble damages, civil penalties and the cost of the civil action under the *qui tam* provisions of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 *et seq.*

1028. Tenn. Code Ann. §§71-5-182 (a)(1)(B) provides liability for any person who-

> Makes, uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the State knowing such record or statement is false

1029. Pursuant to Tennessee's Medicaid False Claims Act, a person who violates this provision Tenn. Code Ann. §§71-5-181 *et seq.* is liable to the State for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand

dollars ($10,000), plus three (3) times the amount of damages which the State sustains because of the act of that person.

1030. Defendants violated Tenn. Code Ann. §71-5-182(a)(1) and knowingly made or used or caused to be made or used hundreds of thousands of records they knew to be false to get false claims paid claims they knew to be false to be made, used and presented to the State of Tennessee from at least 1998 to the present by its violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best Pricing Requirements, as described herein. The false records caused to be made and used and the false claims caused to be made by Defendants illegal conduct failed to disclose the material violations of the AKS and other federal and state laws, in violation of Tenn. Code Ann. §71-5-182(a)(1)(A).

1031. At all times relevant to this Complaint, Defendants acted with the requisite scienter in violating the federal and state law cited herein.

1032. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs and unaware of Defendants' fraudulent and illegal practices, paid the false claims submitted by healthcare providers in connection therewith.

1033. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Tennessee in connection with Defendants' fraudulent and illegal practices.

1034. Had the State of Tennessee known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care

providers in connection with Defendants' fraudulent and illegal practices.

1035. As a result of Defendants' violations of Tenn. Code Ann. §71-5-182(a)(1) , the State of Tennessee has been damages in an amount far in excess of millions of dollars exclusive on interest.

1036. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Tenn. Code Ann. §71-5-183(a)(1) on behalf of herself and the State of Tennessee.

1037. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

COUNT FIFTY-SEVEN
Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(C)

1038. Plaintiffs Arriazola and the State of Tennessee reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1039. This is a qui tam action brought by Arriazola on behalf of the State of Tennessee to recover treble damages, civil penalties and the cost of the civil action under the *qui tam* provisions of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 *et seq.*

1040. Tenn. Code Ann. §§71-5-182 (a)(1)(C) provides liability for any person who-

> Conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;

1041. Pursuant to Tennessee's Medicaid False Claims Act, a person who violates this provision Tenn. Code Ann. §§71-5-181 *et seq.* is liable to the State for a civil

penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the State sustains because of the act of that person.

1042. Defendants violated Tenn. Code Ann. §71-5-182(a)(1)(C) and conspired to get hundreds of thousands of claims they knew to be false paid by the State of Tennessee from at least 1998 to the present by its violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best Pricing Requirements, as described herein. The false records caused to be made and used and the false claims caused to be made by Defendants illegal conduct failed to disclose the material violations of the AKS and other federal and state laws, in violation of Tenn. Code Ann. §71-5-182(a)(1)(A).

1043. At all times relevant to this Complaint, Defendants acted with the requisite scienter in violating the federal and state law cited herein.

1044. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs and unaware of Defendants' fraudulent and illegal practices, paid the false claims submitted by healthcare providers in connection therewith.

1045. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Tennessee in connection with Defendants' fraudulent and illegal practices.

1046. Had the State of Tennessee known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care

providers in connection with Defendants' fraudulent and illegal practices.

1047. As a result of Defendants' violations of Tenn. Code Ann. §71-5-182(a)(1), the State of Tennessee has been damages in an amount far in excess of millions of dollars exclusive on interest.

1048. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Tenn Code Ann. §71-5-183(a)(1) on behalf of herself and the State of Tennessee.

1049. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

COUNT FIFTY-EIGHT
Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(D)

1050. Plaintiffs Arriazola and the State of Tennessee reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1051. This is a qui tam action brought by Arriazola on behalf of the State of Tennessee to recover treble damages, civil penalties and the cost of the civil action under the *qui tam* provisions of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 *et seq.*

1052. Tenn. Code Ann. §§71-5-182 (a)(1)(D) provides liability for any person who-

> Makes, uses, or causes to be made or used, a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State, relative to the Medicaid program, knowing such record or statement is false;

1053. Pursuant to Tennessee's Medicaid False Claims Act, a person who

violates this provision Tenn. Code Ann. §§71-5-181 *et seq.* is liable to the State for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the State sustains because of the act of that person.

1054. Defendants violated Tenn. Code Ann. §71-5-182(a)(1) and knowingly made or used or caused to be made or used hundreds of thousands of records they knew to be false to get false claims paid claims they knew to be false to be made, used and presented to the State of Tennessee from at least 1998 to the present by its violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best Pricing Requirements, as described herein. The false records caused to be made and used and the false claims caused to be made by Defendants illegal conduct failed to disclose the material violations of the AKS and other federal and state laws, in violation of Tenn. Code Ann. §71-5-182(a)(1)(A).

1055. At all times relevant to this Complaint, Defendants acted with the requisite scienter in violating the federal and state law cited herein.

1056. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs and unaware of Defendants' fraudulent and illegal practices, paid the false claims submitted by healthcare providers in connection therewith.

1057. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Tennessee in connection with Defendants' fraudulent and illegal practices.

1058. Had the State of Tennessee known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers in connection with Defendants' fraudulent and illegal practices.

1059. As a result of Defendants' violations of Tenn. Code Ann. §71-5-182(a)(1) , the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive on interest.

1060. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Tenn. Code Ann. §71-5-183(a)(1) on behalf of herself and the State of Tennessee.

1061. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

COUNT FIFTY-NINE
Tennessee False Claims Act
Tenn. Code Ann. § 4-18-101 *et seq.*

1062. Plaintiffs Arriazola and the State of Tennessee reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1063. This is a qui tam action brought by Arriazola on behalf of the State of Tennessee to recover treble damages, civil penalties and the cost of the civil action under the *qui tam* provisions of the Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.*

1064. Tenn. Code Ann. §4-18-103, titled "Liability for violations," provides:

> (a) Any person who commits any of the following acts shall be liable to the State or to the political subdivision for three (3) times the amount of damages which the State or the political subdivision sustains because of the act of that person. A person who commits any of the

following acts shall also be liable to the State or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and shall be liable to the State or political subdivision for a civil penalty of not less than two thousand five hundred dollars ($ 2,500) and not more than ten thousand dollars ($ 10,000) for each false claim:

(1) Knowingly presents or causes to be presented to an officer or employee of the State or of any political subdivision thereof, a false claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the State or by any political subdivision;

(3) Conspires to defraud the State or any political subdivision by getting a false claim allowed or paid by the State or by any political subdivision;

(7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State or to any political subdivision;

1065. Defendants violated §4-18-103(a)(1), (2), (3) and (7) by knowingly presenting or causing hundreds of thousands of false claims to be presented from at least 1998 to the present by their violation of state and federal laws, including the Anti-Kickback Statute and Best Price Statute, as described herein.

1066. The State of Tennessee, by and through Tennessee-funded health plans, and unaware of Defendants' illegal practices, paid the claims submitted by health care providers and third party payors in connection therewith.

1067. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of Tennessee in connection with Defendants' fraudulent and illegal practices.

1068. Had the State of Tennessee known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers in connection with Defendants' fraudulent and illegal practices.

1069. As a result of Defendants' violations of Tenn. Code Ann. §§4-18-103, the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive on interest.

1070. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Tenn. Code Ann. §§4-18-103 on behalf of herself and the State of Tennessee.

1071. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

COUNT SIXTY
The Rhode Island False Claims Act,
R.I. Gen. Laws § 9-1.1-1 *et seq.*

1072. Plaintiffs Arriazola and the State of Rhode Island reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1073. This is a *qui tam* action brought by Arriazola on behalf of the State of Rhode Island to recover treble damages, civil penalties and the cost of the civil action under the *qui tam* provisions of the Rhode Island False Claims Act, known as the State False Claims Act, Chapter 9-1.1, § 9-1.1-1 *et seq.*

1074. The Rhode Island False Claims Act, § 9-1.1-3 (a) provides for liability for any person who:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the guard a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid; or

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State.

1075. Pursuant to the Rhode Island False Claims Act, any person who violates any or all of these is liable to the State for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the State sustains because of the act of that person. A person who violates § 9-1.1-3 (a) shall also be liable to the State for the costs of a civil action brought to recover any such penalty or damages.

1076. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Rhode Island. Amgen, at all times relevant to this action, has operated and continues to operate pharmaceutical distribution facilities in the State of Rhode Island.

1077. By virtue of the conduct alleged herein, including off-label marketing and the exchange of kickbacks and submissions of non-reimbursable claims described above, since at least 1998 Defendant Amgen has knowingly: a) presented or caused to be presented to the Rhode Island Medicaid program and other Rhode Island funded health care programs false claims for payment to approval, b) used or made or caused to be made or used false or fraudulent records to accomplish this purpose, c) conspired to defraud the State of Rhode

Island by getting false or fraudulent claims allowed or paid, and d) made, used, or caused to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit monies or property to the State.

1078. The claims and records presented or caused to be presented as a result of the Defendants illegal practices described here failed to disclose the material violations of the Anti-Kickback Statute, the Stark Act, Best Pricing Requirements and other state and federal laws, in further violation of the Rhode Island False Claims Act, § 9-1.1-3 (a)(1), (2), (3) and (7).

1079. Compliance with applicable Medicare, Medicaid and various other state and federal laws cited herein was an implied condition, and upon information and belief, also

1080. The State of Rhode Island, by and through the Rhode Island Medicaid Program, unaware of Defendants' fraudulent and illegal practices, paid for claims that otherwise would not have been allowed.

1081. Has the State of Rhode Island known that Defendants were violating state and federal laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

1082. By reason of these improper payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

1083. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Rhode Island False Claims Act § 9-1.1-4 on behalf of herself and the State of Tennessee.

1084. This Court is requested to accept pendant jurisdiction of this related state

claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

COUNT SIXTY-ONE
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.002(1)-(2)

1085. Plaintiffs Arriazola and the State of Texas reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1086. This is a *qui tam* action brought by Arriazola on behalf of the State of Texas to recover double damages and civil penalties under the V.T.C.A. Human Resources Code § 36.001 *et seq.*

1087. The V.T.C.A. Hum. Res. Code §36.002 provides liability for any person who-

(1) Knowingly makes or causes to be made a false statement or misrepresentation of a material fact:
   (a) On an application for a contract, benefit, or payment under the Medicaid program; or
   (b) That is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program.

(2) Knowingly concealing or failing to disclose an event:
   (a) That the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of
      (i) the person; or
      (ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
   (b) To permit a person to receive a benefit or payment that is authorized or that is greater than the payment or benefit that is authorized;

1088. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Texas.

1089. By virtue of the conduct alleged herein, including off-label marketing and the exchange of kickbacks and submissions of non-reimbursable claims described above, since at least 1998 Defendants knowingly and intentionally made or caused to be made false statements and misrepresentations of material facts on applications for payments under the Texas Medicaid program.

1090. The claims and records presented or caused to be presented as a result of the Defendants' illegal practices described here failed to disclose the material violations of the Anti-Kickback Statute, the Stark Act, Best Pricing Requirements and other state and federal laws, in further violation of the Tex. Hum. Res. Code §36.002 (1)-(2).

1091. Compliance with applicable Medicare, Medicaid and various other state and federal laws cited herein was an implied condition, and upon information and belief, also an express condition of payment of claims submitted to State of Texas in connection Defendants' fraudulent and illegal practices.

1092. The State of Texas, by and through the Texas Medicaid Program, unaware of Defendants' fraudulent and illegal practices, paid for claims that otherwise would not have been allowed.

1093. Had the State of Texas known that Defendants were violating state and federal laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

1094. By reason of Defendants' illegal practices and violations of the Texas Human Res. Code §35.002, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

1095. Defendants did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

1096. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Texas Human Res. Code §36.101 on behalf of himself and the State of Texas.

1097. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

COUNT SIXTY-TWO
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.002(4)(b)

1098. Plaintiffs Arriazola and the State of Texas reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1099. This is a *qui tam* action brought by Arriazola on behalf of the State of Texas to recover double damages, civil penalties and litigation costs under the Texas Hum. Res. Code § 36.001 *et seq.*

1100. The Texas Hum. Res. Code §36.002(4)(b) provides liability for any person who-

> (4) Knowingly or intentionally makes, causes to be made, induced, or seeks to induce the making of a false statement or misrepresentation of a material fact concerning:
>
> (b) Information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program.

1101. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Texas.

1102. By virtue of the conduct alleged herein, including off-label marketing and the exchange of kickbacks and submissions of non-reimbursable claims described above, in violation of Tex. Hum. Res. Code §36.002(4)(b), since at least 1998 Defendants knowingly and intentionally have made, caused to be made, induced and sought to induce the making of false statements or misrepresentations of material facts concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program.

1103. The false statements or misrepresentations of material facts made, caused to be made, induced or sought to be induced as a result of the Defendants' illegal practices described here failed to disclose the material violations of the Anti-Kickback Statute, the Stark Act, Best Pricing Requirements and other state and federal laws, in further violation of the Tex. Hum. Res. Code §36.002 4(B).

1104. Compliance with applicable Medicare, Medicaid and various other state and federal laws cited herein was an implied condition, and upon information and belief, also an express condition of payment of claims submitted to State of Texas in connection Defendants' fraudulent and illegal practices.

1105. The State of Texas, by and through the Texas Medicaid Program, unaware of Defendants' fraudulent and illegal practices, paid for claims that otherwise would not have been allowed.

1106. Had the State of Texas known that Defendants were violating state and federal laws cited herein, it would not have paid the claims submitted by health care

providers and third party payers in connection with Defendants' fraudulent and illegal practices.

1107. By reason of Defendants' illegal practices and violations of the Texas Human Res. Code §35.002, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

1108. Defendants did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

1109. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Texas Human Res. Code §36.101 on behalf of himself and the State of Texas.

1110. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

COUNT SIXTY-THREE
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.002(5)

1111. Plaintiffs Arriazola and the State of Texas reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1112. This is a *qui tam* action brought by Arriazola on behalf of the State of Texas to recover double damages, civil penalties and litigation costs under the Texas Hum. Res. Code § 36.001 *et seq.*

1113. The Texas Hum. Res. Code §36.002(5) provides liability for any person who-

> (5) Except as authorized under the Medicaid program, knowingly or intentionally charges, solicits, accepts or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program…

1114. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Texas.

1115. By virtue of the conduct alleged herein, including off-label marketing and the exchange of kickbacks, rebates, gifts and other in cash or in kind remuneration as a condition of provision of a service or continuation of service to a Medicaid recipient and submissions of non-reimbursable claims described above, in violation of Tex. Hum. Res. Code §36.002(4)(b), since at least 1998.

1116. The conduct including the exchange of kickbacks, rebates, gifts and other valuable remuneration further violated the Anti-Kickback Statute, the Stark Act, Best Pricing Requirements and other state and federal laws, in further violation of the Tex. Hum. Res. Code §36.002 as well as violated that provision as the conduct resulted in the knowing submission of false claims to the Texas Medicaid program.

1117. Compliance with applicable Medicare, Medicaid and various other state and federal laws cited herein was an implied condition, and upon information and belief, also an express condition of payment of claims submitted to State of Texas in connection Defendants' fraudulent and illegal practices.

1118. The State of Texas, by and through the Texas Medicaid Program, unaware of Defendants' fraudulent and illegal practices, paid for claims that otherwise would not have been allowed.

1119. Had the State of Texas known that Defendants were violating state and federal laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

1120. By reason of Defendants' illegal practices and violations of the Texas Human Res. Code §35.002, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

1121. Defendants did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

1122. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Texas Human Res. Code §36.101 on behalf of himself and the State of Texas.

1123. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

COUNT SIXTY-FOUR
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(A)(1)

1124. Plaintiffs Arriazola and the Commonwealth of Virginia reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1125. This is a *qui tam* action brought by Arriazola on behalf of the State of Virginia to recover double damages, civil penalties and litigation costs under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1 *et seq.*

1126. The Virginia Fraud Against Taxpayers Act, §8.01-216.3(A)(1), provides for liability for any person who-

> Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval.

1127. Pursuant to the Virginia Fraud Against Taxpayers Act, any person who violates any subsection of §8.01-216.3(A) shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

1128. Defendants violated Virginia Fraud Against Taxpayers Act, §8.01-216.3(A)(1) and knowingly caused hundreds of thousands of claims they knew to be false to be made, used and presented to the Commonwealth of Virginia from at least 1998 to the present by its violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best Pricing Requirements, as described herein. The claims caused to be submitted failed to disclose the material violations of the AKS and other federal and state laws, in violation of Va. Code Ann. §8.01-216.3(A)(1).

1129. At all times relevant to this Complaint, Defendants acted with the requisite

scienter in violating the federal and state law cited herein.

1130. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state health care programs and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by healthcare providers in connection therewith.

1131. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' fraudulent and illegal practices.

1132. Had the Commonwealth of Virginia known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers in connection with Defendants' fraudulent and illegal practices.

1133. As a result of Defendants' violations of Va. Code Ann. §8.01-216.3(A)(1), the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive on interest.

1134. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Virginia Fraud Against Taxpayers Act 8.01-216.5(A) on behalf of herself and the Commonwealth of Virginia.

1135. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

COUNT SIXTY-FIVE
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(A)(2)

1136. Plaintiffs Arriazola and the Commonwealth of Virginia reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1137. This is a *qui tam* action brought by Arriazola on behalf of the State of Virginia to recover double damages, civil penalties and litigation costs under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1 *et seq.*

1138. The Virginia Fraud Against Taxpayers Act, §8.01-216.3(A)(2), provides for liability for any person who-

> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth.

1139. Pursuant to the Virginia Fraud Against Taxpayers Act, any person who violates any subsection of §8.01-216.3(A) shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

1140. Defendants have violated Virginia Fraud Against Taxpayers Act, §8.01-216.3(A)(2) and have knowingly made, used, or has caused to be made or used, hundreds of thousands of false records or statements to get false or fraudulent claims paid or approved by the Commonwealth from at least 1998 to the present by its violation of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best Pricing Requirements, as described herein. The claims caused to be submitted failed to disclose the material violations of the AKS and other federal and state laws, in violation

of Va. Code Ann. §8.01-216.3(A)(1).

1141. At all times relevant to this Complaint, Defendants acted with the requisite scienter in violating the federal and state law cited herein.

1142. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state health care programs and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by healthcare providers in connection therewith.

1143. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' fraudulent and illegal practices.

1144. Had the Commonwealth of Virginia known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers in connection with Defendants' fraudulent and illegal practices.

1145. As a result of Defendants' violations of Va. Code Ann. §8.01-216.3(A)(2), the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive on interest.

1146. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Virginia Fraud Against Taxpayers Act 8.01-216.5(A) on behalf of herself and the Commonwealth of Virginia.

1147. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts

separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

COUNT SIXTY-SIX
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(A)(3)

1148. Plaintiffs Arriazola and the Commonwealth of Virginia reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1149. This is a *qui tam* action brought by Arriazola on behalf of the State of Virginia to recover double damages, civil penalties and litigation costs under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1 *et seq.*

1150. The Virginia Fraud Against Taxpayers Act, §8.01-216.3(A)(3), provides for liability for any person who-

> Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

1151. Pursuant to the Virginia Fraud Against Taxpayers Act, any person who violates any subsection of §8.01-216.3(A) shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

1152. Defendants have violated Virginia Fraud Against Taxpayers Act, §8.01-216.3(A)(3) and have knowingly conspired to defraud the Commonwealth of Virginia by getting hundreds of thousands of false or fraudulent claims allowed or paid by the Commonwealth from at least 1998 to the present. Defendants' overt acts in furtherance of the conspiracy have violated federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best Pricing Requirements, as described herein. The claims

caused to be submitted by and through Defendants unlawful confederacy failed to disclose the material violations of the AKS and other federal and state laws, in violation of Va. Code Ann. §8.01-216.3(A)(1).

1153. At all times relevant to this Complaint, Defendants acted with the requisite scienter in violating the federal and state law cited herein.

1154. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state health care programs and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by healthcare providers in connection therewith.

1155. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' fraudulent and illegal practices.

1156. Had the Commonwealth of Virginia known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers in connection with Defendants' fraudulent and illegal practices.

1157. As a result of Defendants' violations of Va. Code Ann. §8.01-216.3(A)(3), the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive on interest.

1158. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Virginia Fraud Against Taxpayers Act 8.01-216.5(A) on behalf of herself and the Commonwealth of Virginia.

1159. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

COUNT SIXTY-SEVEN
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(A)(7)

1160. Plaintiffs Arriazola and the Commonwealth of Virginia reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1161. This is a *qui tam* action brought by Arriazola on behalf of the State of Virginia to recover double damages, civil penalties and litigation costs under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1 *et seq.*

1162. The Virginia Fraud Against Taxpayers Act, §8.01-216.3(A)(7), provides for liability for any person who-

> Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth.

1163. Pursuant to the Virginia Fraud Against Taxpayers Act, any person who violates any subsection of §8.01-216.3(A) shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

1164. Defendants have violated Virginia Fraud Against Taxpayers Act, §8.01-216.3(A)(7) and have knowingly made or used or caused to be made or used hundreds of thousands of false records and/or statements to conceal, avoid, or decrease an obligation

to pay or transmit money or property to the Commonwealth by and through their intentional and/or knowing violations of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best Pricing Requirements, as described herein.

1165. At all times relevant to this Complaint, Defendants acted with the requisite scienter in violating the federal and state law cited herein.

1166. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state health care programs and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by healthcare providers in connection therewith.

1167. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' fraudulent and illegal practices.

1168. Had the Commonwealth of Virginia known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers in connection with Defendants' fraudulent and illegal practices.

1169. As a result of Defendants' violations of Va. Code Ann. §8.01-216.3(A)(7), the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive on interest.

1170. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Virginia Fraud Against Taxpayers Act 8.01-216.5(A) on behalf of herself and the Commonwealth of Virginia.

1171. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

COUNT SIXTY-EIGHT
New Jersey False Claims Act
N.J. Stat. § 2A: 32C-3

1172. Plaintiffs Arriazola and the State of New Jersey reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

1173. This is a *qui tam* action brought by Arriazola on behalf of the State of New Jersey to recover civil penalties, treble damages and litigation costs under the New Jersey False Claims Act.

1174. The New Jersey False Claims Act, §3 provides that any person who commits any of the following acts shall be jointly and severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C. §3729 *et seq.*), as may be adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub.L.101-410, for each false claim, plus three times the amount of damages which the State sustains because of the act of that person:

a. Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false claim for payment or approval;

b. Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the State;

c. Conspires to defraud the State by getting a false claim allowed or paid by the State;

g. Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

1175. Defendants have violated the New Jersey False Claims Act by and through their intentional and/or knowing violations of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best Pricing Requirements, as described herein, as well as through their illegal off-label promotional schemes related to FDA-regulated prescription drugs.

1176. Defendants knowingly presented or caused to be presented false or fraudulent claims to the New Jersey Medicaid program and knowingly made, used or caused to be made or used, false statements to get said claims paid by the Medicaid Program. Prescriptions for the purposes of off-label uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendants. As a result of this illegal scheme, these claims were improper in whole pursuant to the New Jersey False Claims Act.

1177. Defendants further violated the New Jersey False Claims Act by conspiring to defraud the State of New Jersey by getting false or fraudulent claims paid by the State and further have knowingly made, used, or caused to be made or used hundreds of thousands of false records or statements to conceal, avoid, or decrease their obligations to pay or transmit money or property to the State.

1178. The claims presented or caused to be presented and the records and statements made or used or caused to be made or used were false *inter alia* because the records and claims knowingly inflated the cost to the State of New Jersey Medicaid program due to the Defendants concealment of their unlawful promotional activities

including undisclosed rebates, kickbacks, gifts and other illegal remuneration.

1179. It is illegal and further violative of the New Jersey False Claims Act to defray the costs of illegal kickbacks and other unlawful promotional marketing schemes by failing to disclose to Government purchasers of prescription drugs the existence and amount of discounts given to private purchasers for prescription drugs. It is also illegal to falsely report the true cost of a prescription drug.

1180. The State of New Jersey, by and through the New Jersey Medicaid program and other state health care programs and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by healthcare providers in connection therewith.

1181. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied condition, and upon information and belief an express condition, of payment of claims submitted to the State of New Jersey in connection with Defendants' fraudulent and illegal practices.

1182. Had the State of New Jersey known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers in connection with Defendants' fraudulent and illegal practices.

1183. As a result of Defendants' violations of the New Jersey False Claims Act, the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive on interest.

1184. At all times relevant to the complaint, the Defendants were acting with the requisite scienter in engaging in the conduct which violated the state and federal laws set forth herein.

1185. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the New Jersey False Claims Act on behalf of herself and the State of New Jersey.

1186. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

COUNT SIXTY-NINE
Montana False Claims Act
Mont. Code Ann. § 17-8-401 *et seq.*

1187. Plaintiffs Arriazola and the State of Montana reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1188. This is a claim for treble damages and civil penalties under the Montana False Claims Act. Mont. Code Ann., §17-8-401 *et seq.*

1189. Section 3 of the Montana False Claims Act provides for liability for *inter alia* any person who engages in any or all of the following conduct:

(a) Knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;

(b) Knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;

(c) Conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity;

(g) Knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors; or

(h) As a beneficiary of an inadvertent submission of a false claim to the governmental entity, subsequently discovering the falsity of the claim and failing to disclose the false claim to the governmental entity within a reasonable time after discovery of the false claim.

1190. Amgen, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Montana.

1191. By virtue of the conduct alleged herein, including the exchange of kickbacks and submissions of non-reimbursable claims described above and the off-label marketing scheme described above, Defendants knowingly violated each of the above subsections of the Montana False Claims Act by and through their intentional and/or knowing violations of federal and state laws, including the Anti-Kickback Statute, the Stark Act and Best Pricing Requirements, as described herein.

1192. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of Defendants' illegal conduct, paid for claims that otherwise would not have been allowed.

1193. By reason of these improper payments, the Montana Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

1194. Arriazola is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Montana False Claims Act on behalf of herself and the State of Montana.

1195. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

COUNT SEVENTY
Oklahoma Medicaid False Claims Act
63 Okla. Stat. § 5053, *et seq.*

1196. Plaintiffs Arriazola and the State of Oklahoma reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1197. This is a claim for treble damages and civil penalties under the Oklahoma

Medicaid False Claims Act, 63 Okla. Stat. §5053, *et seq.*

1198. Section 5053.1 B of the Oklahoma Medicaid False Claims Act provides for liability for any person who, *inter alia*:

1. Knowingly presents or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

3. Conspires to defraud the State by getting a false or fraudulent claim allowed or paid; and,

7. Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State…

1199. Section 5053.1 B of the Oklahoma Medicaid False Claims Act further provides that any person who engages in any of the foregoing acts is liable to the State of Oklahoma for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages which the State sustains because of the act of that person.

1200. Defendant Amgen, acting in concert with its co-Defendants, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Oklahoma.

1201. By virtue of the conduct alleged herein, including the exchange of kickbacks and submissions of non-reimbursable claims described above and the off-label marketing scheme described above and their intentional and/or knowing violations of federal and state laws, including the Anti-Kickback Statute, the Stark Act, and Best Pricing Requirements, as described herein, Defendants knowingly violated each of the above cited provisions of the Oklahoma Medicaid False Claims Act.

1202. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of Defendants' illegal conduct, paid for claims that otherwise would not have been allowed.

1203. By reason of these improper payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

1204. Arriazola is a private person with direct and independent knowledge of the allegations in this Third Amended Complaint , who has brought this action pursuant to the Oklahoma Medicaid False Claims Act on behalf of herself and the State of Oklahoma.

1205. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

COUNT SEVENTY-ONE
Nevada False Claims Act
Nev. Rev. Stat. Ann. §357.040(1)(a)-(c), (g)

1206. Plaintiffs Arriazola and the State of Nevada reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1207. This is a claim for treble damages and penalties under the Nevada False Claims Act.

1208. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

1209. By virtue of the acts described above, Defendants knowingly made, used,

or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

1210. By virtue of the acts described above, Defendants conspired with each other and with others to defraud Nevada by inducing the Nevada State Government to pay or approve false or fraudulent claims.

1211. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Nevada State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the Defendants.

1212. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

1213. By reason of the Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1214. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

1215. Arriazola is a private person with direct and independent knowledge of the allegations in this Third Amended Complaint , who has brought this action pursuant to the Nevada False Claims Act on behalf of herself and the State of Nevada.

1216. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

COUNT SEVENTY-TWO
Wisconsin False Claims For Medical Assistance Act
Wis. Stat §20.931 et seq

1217. Plaintiffs Arriazola and the State of Nevada reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1218. This is a claim for treble damages and penalties under the Wisconsin False Claims Act.

1219. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

1220. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

1221. By virtue of the acts described above, Defendants conspired with each other and with others to defraud Wisconsin by inducing the Wisconsin State Government to pay or approve false or fraudulent claims.

1222. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Wisconsin State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of

money or property owed to the State by the Defendants.

1223. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

1224. By reason of the Defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1225. The State of Wisconsin is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

1226. Arriazola is a private person with direct and independent knowledge of the allegations in this Third Amended Complaint , who has brought this action pursuant to the Wisconsin False Claims Act on behalf of herself and the State of Wisconsin.

1227. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

COUNT SEVENTY-THREE
Connecticut False Claims Act
Chapter 319v, Sec. 17b-301 *et seq.*

1228. Plaintiffs Arriazola and the State of Connecticut reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1229. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

1230. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut Government for payment or approval.

1231. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut Government to approve and pay such false and fraudulent claims.

1232. By virtue of the acts described above, Defendants conspired with each other and with others to defraud Connecticut by inducing the Connecticut Government to pay or approve false or fraudulent claims.

1233. The Connecticut Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

1234. By reason of the Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1235. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

1236. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

COUNT SEVENTY-FOUR
Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-1-104 *et seq.*

1237. Plaintiffs Arriazola and the State of Colorado reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1238. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act.

1239. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

1240. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

1241. By virtue of the acts described above, Defendants conspired with each other and with others to defraud Colorado by inducing the Colorado State Government to pay or approve false or fraudulent claims.

1242. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

1243. By reason of the Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1244. The State of Colorado is entitled to the maximum penalty of $10,000 for

each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

1245. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

COUNT SEVENTY-FOUR
Maryland False Health Claims Act of 2010
Subtitle 6, False Claims Against State Health Plans and
State Health Programs, § 2-601 *et seq.*

1246. Plaintiffs Arriazola and the State of Maryland reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1247. This is a claim for treble damages and penalties under the Maryland False Health Claims Act of 2010, Subtitle 6.

1248. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

1249. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

1250. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal business practices.

1251. By reason of the Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

1252. The State of Maryland is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

1253. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

COUNT SEVENTY-FIVE
Minnesota False Claims Act
Minn. Stat. § 15C.01 *et seq.*

1254. Plaintiffs Arriazola and the State of Minnesota reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1255. This is a claim for treble damages and penalties under the Minnesota False Claims Act.

1256. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

1257. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Minnesota State Government to approve and pay such false and fraudulent claims.

1258. By virtue of the acts described above, Defendants conspired with each

other and with others to defraud Minnesota by inducing the Minnesota State Government to pay or approve false or fraudulent claims.

1259. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

1260. By reason of the Defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1261. The State of Minnesota is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

1262. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

COUNT SEVENTY-SIX
North Carolina False Claims Act
N.C. Gen. Stat. §§1-605 *et seq.*

1263. Plaintiffs Arriazola and the State of North Carolina reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1264. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

1265. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government

for payment or approval.

1266. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

1267. By virtue of the acts described above, Defendants conspired with each other and with others to defraud North Carolina by inducing the North Carolina State Government to pay or approve false or fraudulent claims.

1268. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

1269. By reason of the Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1270. The State of North Carolina is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

1271. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

COUNT SEVENTY-SEVEN
New York City False Claims Act
New York City Administrative Code §7-801-§7-810

1272. Plaintiffs Arriazola and New York City reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1273. This is a claim for treble damages and penalties against Defendants on behalf of the City of New York under the New York City False Claims Act, New York City Administrative Code §7-801-§7-810.

1274. By virtue of the above-described acts, among others, Defendants knowingly and willfully promoted their drugs for non medically accepted uses.

1275. By virtue of the above-described acts, Defendants knowingly made or caused to be made false claims for Defendants drugs to the New York City Government.

1276. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York City Government to approve and pay such false and fraudulent claims.

1277. The New York City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

1221. By reason of the Defendant's unlawful acts, the City of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against defendant Defendants Inc. as follows:

a. That by reason of the aforementioned violations of the New York City False Claims Act provisions that this Court enter judgment in Plaintiff's favor and against Pfizer in an amount equal to not less than two times and not more than three times the amount of damages that the City of New York has sustained because of Pfizer's actions, plus a civil penalty of not less than $5,000 and not more than $15,000 for each violation of the New York City False Claims Act, New York City Administrative Code §7-801-§7-810;

b. That Relators, as *Qui Tam* Plaintiffs, be awarded the maximum amount allowed pursuant New York City Administrative Code § 704(i) and/or any other applicable provision of law;

c. That Relators be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

1278. d. That Plaintiffs and Relators have such other and further relief that this Court deems just and proper.

COUNT SEVENTY-EIGHT
City of Chicago False Claims Act
Municipal Code of Chicago §1-22-010-§1-22-060

1279. Plaintiffs Arriazola and the City of Chicago reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

1280. This is a claim for treble damages and penalties against all Defendant on behalf of the City of Chicago under the Chicago False Claims Act, Municipal Code of Chicago §1-22-010-§1-22-060.

1281. By virtue of the above-described acts, among others, Defendants knowingly and willfully promoted their drugs for non medically accepted uses.

1282. By virtue of the above-described acts, Defendants knowingly made or caused to be made false claims for Defendants drugs to the City of Chicago.

1283. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City of Chicago to approve and pay such false and fraudulent claims.

1284. The Chicago City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

1285. By reason of the Defendant's unlawful acts, the City of Chicago has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

JURY DEMAND

1286. Plaintiffs demand trial by jury on all claims.

PRAYER

WHEREFORE, Plaintiff Arriazola on behalf of herself and the Government Plaintiffs, respectfully requests that this Court enter Judgment in her favor and against the Defendants as follows:

A. That the Defendants be enjoined from violating the provisions of 31 U.S.C. § 3729 *et seq.* and the equivalent State law claims for relief;

B. That this Court enter Judgment against each Defendant in an amount equal to three times the amount of damages the United States has sustained as a result of Defendants' actions, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each violation of 31 U.S.C. § 3729 *et seq*;

C. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained as a result of

Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of the California False Claims Act, § 12651(A);

D. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained as a result of Defendants' actions, plus a civil penalty of not less than $11,000.00 for each violation of 6 Del C. § 1201(a);

E. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained as a result of Defendants' actions, plus a civil penalty of not less than $11,000.00 for each violation of Fl. Stat. Ann. § 68.082;

F. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained as a result of Defendants' actions, plus a civil penalty of not less than $11,000.00 for each violation of Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168 *et. seq.*

G. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of Haw. Rev. Stat. § 661-21(a);

H. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of 740 Ill. Comp. Stat. § 175/3(a);

I. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained as a result of Defendants' actions, plus a civil penalty of at least $5,000.00 for each violation of Ind. Code. Ann. § 5-11-5.5;

J. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of La. Rev. Stat. § 46:437 *et seq*;

K. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of Mass. Gen. L. Ch. 12 § 5B;

L. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained as a result of Defendants' actions, plus a civil penalty of not more than $10,000 for each violation of Mich. Comp. Laws § 400.601 *et seq.*, as amended 2008 PA 421; and Michigan Public Acts, 1977 PA 72, as amended by 1984 PA 333, as amended by 2005 PA 337, as amended by 2008 PA 421;

M. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of Mont. Code Ann. § 17-8-401;

N. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of Nev. Rev. Stat. Ann. § 357.040(1);

O. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of N.H. Rev. Stat. Ann. § 167:61-b(I);

P. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of N.J. Stat. § 2A:32C-1 *et seq.*;

Q. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained as a result of Defendants' actions, plus a civil penalties of not less than $10,000 for each violation of N.M. Stat. Ann. § 27-14-1 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.*;

R. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained as a result of Defendants' actions, plus a civil penalty of not less than $12,000.00 for each violation of New York False Claims Act, State Fin. Law § 187, *et seq.*

S. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of the

Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053, *et. seq.*

T. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000 for each violation of Rhode Island's State False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et. seq.*

U. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of Tenn. Code Ann. § 4-18-103(a) and § 71-5-182(a);

V. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of Tex. Hum. Res. Code Ann. § 36.002;

W. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Virginia has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of Va. Code Ann. § 8.01-216.3(a);

X. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained as a result of Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931, *et. seq.*

Y. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained as a result of

Defendants' actions, plus a civil penalty of not less than $10,000.00 for each violation of D.C. Code Ann. § 2-308.14(a);

Z. That this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained as a result of Defendants' actions, plus a civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b(1);

AA. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of the Connecticut False Claims Act, Chapter 319v, Sec. 17b-301 *et seq.*;

BB. that this court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages Colorado has sustained because of the defendants' actions, plus a civil penalty of $10,000 for each violation of the Colorado Medicaid False Claims Act, Colo. Rev. Stat., § 25.5-1-104 *et seq.*;

CC. that this court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages Maryland has sustained because of the defendants' actions, plus a civil penalty of $11,000 for each violation of the Maryland False Health Claims Act of 2010 (Subtitle 6, False Claims Against State Health Plans and State Health Programs, § 2-601 *et seq.*);

DD. that this court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages Minnesota has sustained because of the defendants' actions, plus a civil penalty of $11,000 for each violation of the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*;

EE. that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions plus a civil penalty of $11,000 for each violation of N.C. Gen. Stat. §§1-605 et seq.;

FF. that by reason of the aforementioned violations of the New York City False Claims Act provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the City of New York has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $15,000 for each violation of the New York City False Claims Act, New York City Administrative Code §7-801-§7-810;

GG. that by reason of the aforementioned violations of the Chicago False Claims Act provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the City of Chicago has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of the Municipal Code of Chicago §1-22-010-§1-22-060;

HH. That the Plaintiff be awarded all costs of this action, including reasonable attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d) and the equivalent State statutes set forth above;

II. That the United States, the Plaintiff States, and the Plaintiff be granted such other and further relief as the Court deems just and proper or that is necessary to make the Plaintiffs whole.

Respectfully submitted,

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